No. 06-1539

FILED
MAY 21 2007
OFFICE OF THE CLERK

In The Supreme Court of the United States

MICHAEL and MELISSA MARKOVICH,
Parents of Ashlyn M. Markovich,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

PETITION FOR WRIT OF CERTIORARI WITH APPENDIX

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QUESTIONS PRESENTED

1. What standard should be applied in determining the time certain for the commencement of the statute of limitations in which to bring a claim pursuant to the National Vaccine Compensation Act.

2. Whether, in the case at hand, a two month old acting as though she's tired later in the day of receiving her vaccination is enough to trigger the commencement of the statute of limitations.

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OPINION BELOW

The United States Court of Appeals, Federal Circuit, published its decision reported at 477 F.3d 1353 (App., *infra*., 1-17). Mr. and Mrs. Markovich appealed from a final decision of the United States Court of Federal Claims, Susan G. Braden, J., 69 Fed. Cl. 327 (App., *infra*, 18-42). Finally, the decision of Special Master Sweeney, No. 03-2015V, is attached (App., *infra*, 43-87).

JURISDICTION

The United States Court of Appeals for the Federal Circuit filed its decision and judgment was entered on February 20, 2007. This court has jurisdiction under 28 U.S.C. § 1254(1) to review the Federal Circuit Court's decision on a writ of certiorari.

STATUTORY PROVISION INVOLVED

The National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-1 *et seq.* (2000 & Supp. II 2003), provides in pertinent part:

> §§ 300aa-1 to 300aa-34 (2000 & Supp. II 2003), "Vaccine Act" expressly provides that for vaccines listed in the Vaccine Injury Table ("table"): If a vaccine-related injury occurred as a result of the administration of such vaccine, no Petition may be filed for compensation under their program for such injury after the expiration of 36 months after

> the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury... 42 U.S.C. § 300aa-16(a)(2) (emphasis added).

STATEMENT OF THE CASE

1. Cases under the Vaccine Act are adjudicated in the first instance by a Special Master. 42 U.S.C. § 300aa-12(d)(3) (Supp. IV 2003). On motion by party, the Court of Federal Claims will review the Special Master's decision. That court may either uphold the decision, or "set aside any findings of fact or conclusions of law***found to be arbitrary, capricious and abusive discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law." 42 U.S.C. § 300aa-12(3)(2)(B) (Supp. IV 2003). The decision of the Court of Federal Claims is subject to review in the United States Court of Appeals for the Federal Circuit. 42 U.S.C. § 300aa-12(f) (Supp. V 2003).

2. On July 10, 2000, when Ashlyn Markovich was approximately two months old, she received a series of vaccinations, including the vaccinations against diphtheria, tetanus (commonly known as lock jaw), pertussis (whopping cough), polio and Haemophilus Influenza Type B. That same day, the Markovichs observed Ashlyn having an eye blinking episode to which they thought she was simply tired. App., *infra*, 3. For approximately the next 50 days, the Markovichs went on with their life with no concerns for Ashlyn's health. There were

occasional episodes in which the Markovichs thought Ashlyn was tired because of the blinking of her eyes. *Id.* However, on August 30, 2000, Ashlyn became unresponsive for approximately 20 minutes, during which time all of her extremities jerked aggressively. The Markovichs immediately called 911 and Ashlyn was taken to the Fairview Ridge Emergency Room, where she was diagnosed with having suffered a grand-mall seizure. *Id.* Another seizure occurred about two weeks later. Ashyln continued to suffer seizures almost daily, sometimes experiencing 3 or more seizures a day. At times, Ashlyn had seizures that consisted of eye blinking episodes between 150 and 500 times per day through the year 2000. *Id.* at 4.

On January 29, 2002, Ashlyn was admitted to the Mayo Clinic for an evaluation at which time a neurologist diagnosed Ashlyn as having experienced "four types of seizures: (1) repeated eye blinking; (2) clonic movement of the face, arm and leg; (3) generalized seizures with or without focal onset; and (4) partial motor seizures." *Id.*

4. On August 29, 2003, the Markovichs filed a petition for compensation under the Act, alleging that Ashlyn suffered the seizures as a result of her vaccination on July 10, 2000. *Id.* On January 27, 2004, the Special Master held a status conference indicating that an "onset hearing" was necessary in order to determine whether the Markovichs' Petition was time-barred as having been filed more than three years after the date on which the first symptom or manifestation of onset of the injury occurred. On November 5, 2004, the Special Master

held the onset hearing to determine whether the onset of the seizures occurred on July 10, 2000 or on August 30, 2000. *Id.* at 5.

5. On July 22, 2005, the Special Master denied compensation. *Id.* The Special Master was persuaded by the testimony of Petitioners' own expert, Dr. Jean-Ronel Corbier. "Throughout his testimony, Dr. Corbier stated that Ashlyn's eye blinking would have made him suspicious and prompted him to ask further questions and conduct an evaluation and order testing." App., *infra*, 75. The Special Master concluded that Dr. Corbier's testimony proved that from an objective standpoint, onset was manifest even though the parents did not recognize its significance. *Id.* at 77. Further, the Special Master concluded that because the parents were aware that eye blinking episodes began on July 10, 2000, regardless of whether they thought there was an injury of any type, and continued until the August 30, 2000 seizure was relevant. *Id.* at 73.

6. The United States Court of Federal Claims agreed with the Special Master's decision and denied Petitioners' Motion for Review claiming that the onset of Ashlyn's seizure disorder was July 10, 2000. Again, the Court of Federal Claims was persuaded by Dr. Corbier's testimony. The court put great weight on Dr. Corbier's testimony that Ashlyn's July 10, 2000 eye blinking episode was a result of a cerebral dysfunction and is "linked to" the August 30, 2000 episode. App., *infra*, 32. Further, Dr. Corbier testified that the July 10, 2000 episode was due to some type of cerebral dysfunction... *Id.* at 32-33. Finally, Dr. Corbier testified that Ashlyn's

July 10, 2000 eye blinking episode was an "objective symptom" of a seizure disorder. *Id.* at 33. For the above reasons, the Court of Federal Claims determined that the Special Master's finding that the date of the onset was July 10, 2000 was not arbitrary or capricious.

7. The United States Court of Appeals, Federal Circuit, held that the eye blinking episode of July 10, 2000 constituted the first symptom of the seizure disorder, and was sufficient to trigger the running of the three-year limitations under the Vaccine Injury Act. App., *infra*, 1. The Court of Appeals held that:

> **the first symptom or manifestation of onset, for purposes of § 300aa-16(a)(2), is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large.**

Id. at 16.

The Court of Appeals based its holding on the following:

- Dr. Corbier's testimony that the eye blinking episode of July 10, 2000 was objective evidence of the first symptom of Ashlyn's injury. *Id.*
- Mayo Clinic report of January 29, 2002 that referenced eye blinking as a type of seizure activity. *Id.* at 14.

- A medical record of September 20, 2001 with reference to eye blinking being a sign of seizure disorder. *Id.*
- The Markovichs filed their Petition on August 29, 2003, more than 36 months after the initial symptoms. *Id.* at 16.

REASONS FOR GRANTING THE PETITION

THIS COURT MUST ESTABLISH A MORE DEFINITIVE AND EQUITABLE MANNER OF DETERMINING THE TIME CERTAIN FOR THE COMMENCEMENT OF THE STATUTE OF LIMITATIONS IN CLAIMS BROUGHT PURSUANT TO THE NATIONAL CHILDHOOD VACCINE INJURY ACT.

In claims brought pursuant to the Vaccine Act, the statute of limitations begins to run from the date of the first symptom or manifestation of onset of the alleged vaccine injury. 42 U.S.C. § 300aa-16(a)(2). The Court of Appeals found that the 36 months in which to bring a claim started the day that Ashlyn Markovich received her first vaccination (July 10, 2000). The event that triggered it was an event that her parents thought was a sign of their daughter being tired. There is no reasonable basis for the standard to require the commencement of the statute of limitations to be an event that reasonable parents considered to be normal childhood activity. On July 10, 2000, Ashlyn Markovich, then two months old, was blinking her eyes and her parents thought she was tired. The incident was completely uneventful, short in duration and meaningless. The

only evidence of Ashlyn Markovich's injury or condition as of July 10, 2000 was that she was tired. Showing signs of sleepiness or tiredness on one occasion for a minimal period of time should not be a sufficient to bar an injured vaccine recipient from filing a claim.

For this court to deny Petitioners' Writ of Certiorari would ultimately result in an absurd result. The previous courts have endorsed the proposition that "symptom or manifestation of onset" in seizure disorder cases occur when a parent observes such common everyday events as their child blinking his or her eyes without anything else. A two month old child who is blinking her eyes could as easily be showing signs of being tired as showing a symptom of a disease or injury. The blinking of eyes alone should not be the type of behavior that is considered to clearly or obviously signal the onset of a seizure disorder.

It is common knowledge that a two month old blinking her eyes could be a sign of Ashlyn having something in her eye, batting her eyelashes or simply being tired. As testified to by Petitioners' expert, Dr. Jean-Ronel Corbier, eye blinking alone is not a symptom of anything, without any other symptom, of an injury. App., *infra*, 114.

Parents of immunized children are getting their children immunized to protect their children. The number of children who are adversely affected by the immunization are minuscule when compared to the number of children benefiting from immunizations. There is nothing about the

immunization process that would put a reasonable parent on notice that they should be suspect of side affects, especially epilepsy. There is nothing about the immunization process to warn parents that if their two month old child looks as though she is tired the day of her immunization that it may be the start of epilepsy or seizure disorder. However, the Court of Appeals' decision supports the absurd result that the Vaccine Act's three year statute of limitations begins to run upon an act occurring which was reasonably interpreted by Mr. and Mrs. Markovich to be a sign that their daughter was tired.

Mr. and Mrs. Markovich are not contending that there must be evidence of an injury caused by or related to the vaccination or that there must be a medical diagnosis before the statute of limitations is triggered. However, Congress could not have intended that one, simple, uneventful activity, as common as a baby smiling, is enough to trigger the running of the statute of limitations.

CURRENTLY, AS THE LAW EXISTS, A CHILD THAT DEVELOPS AUTISM FROM VACCINATIONS HAS A DIFFERENT STANDARD TO USE IN CALCULATING THE COMMENCEMENT OF THE STATUTE OF LIMITATIONS THAN A CHILD WITH A SEIZURE DISORDER.

The laws of this country are to apply equally to all parties. However, in light of *Setnes* and the holding of the Court of Appeals in this case, there are currently two standards that are applied to calculate the start of the statute of limitations in

vaccine injury cases. For that reason alone, a standard that is definite and equitable must be established.

Previously, the United States Court of Appeals for the Federal Circuit has held that the statute of limitations in vaccine act cases "begins to run upon the first symptom or manifestation of the onset of injury, even if the Petitioner reasonably would not have known at the time that the vaccine has caused an injury." *Brice v. Sec'y of Health & Human Servs.*, 240 F.3d 1367, 1373 (Fed. Cir. 2001); *Goetz v. Sec'y of Health & Human Servs.*, 45 Fed. Cl. 340, 341 (1999). Congress may have intended the cause of action in vaccine injury table cases to accrue upon occurrence of the first symptom of an injury. However, Congress could certainly not have intended that a cause of action accrues upon an insignificant and/or a normal everyday event interpreted by reasonable parents to be that of a sleepy two month old child.

In *Setnes*, the court addressed the issue of what to do when "symptoms" are subtle or confused with typical child behavior. Although the *Setnes* court involved autism the court held that, where there is no clear start to the injury, prudence mandates that a court addressing the statute of limitations not hinge it decision on the "occurrence of the first symptom." *Setnes v. U.S.*, 57 Fed. Cl. 175, 179 (2003).

The *Setnes* child received his 15-month vaccination on September 11, 1998. After the immunizations, his mother noted that the child

started making a constant humming noise. The *Setnes* child was doing a lot of babbling and, because he was slow to develop words and would no longer respond when he was called his name, his parents thought of a hearing problem. *Setnes*, 57 Fed. Cl. at 175. Later in the same month of the immunization, the child started having temper tantrums, would kick and scream and was at times unconsoleable. The parents then began to notice him running around the kitchen table and would stare at the edge of the table or counter. Finally, the parents began to notice that their son was eating the cardboard boxes that held videotapes. *Id.* at 177.

The *Setnes* parents met with the pediatrician and the pediatrician expressed concern that their child's impediments may be the result of pervasive developmental disorder. On July 15, 2002, the Setnes' filed their Petition. Ultimately, the Petition was allowed because the *Setnes* court ruled that all of the above stated activities were not significant enough to trigger the running of the statute of limitations. The *Setnes* court, because of the difficulty in separating normal childhood activities from symptoms or signs of autism, established an onset date based on contemporaneous medical evaluations as opposed to hindsight. *Id.* at 181.

The *Setnes* court determined that humming, screaming, kicking, babbling and eating videotape cardboard boxes was behavior not recognizable as a sign of a vaccine injury by the medical profession at large. *Id.* The *Setnes* court was not persuaded that the above described behavior clearly or obviously signals the onset of autism. *Id.*

In *Setnes*, the mother was aware that these activities such as humming, screaming, kicking, etc., were not normal childhood activities. For these reasons, she was taking her child to various doctors and the doctors were unable to link the events to an injury and certainly did not link it to a vaccine injury.

However, in the case at hand, the event was so insignificant to Mr. and Mrs. Markovich that they did not even consider medical treatment. There was no injury of any kind, shape or form. However, the Court of Appeals was persuaded that signs of a two month old child being tired (eye blinking) on one occasion of unspecified duration, without any other sign or symptom, clearly and obviously signaled the onset of seizure disorder for Ashlyn Markovich.

Clearly, the message is that autism is so different than epilepsy that the courts are going to hold parents to a different standard. The standard in *Setnes* was such that the courts did not commence the running of the statute of limitations until there was some correlation by the medical community to the injury being autism while, in the case at hand, the statute of limitations began to run because there was a sign that Ashlyn Markovich was tired.

DR. CORBIER'S OPINION THAT THE EYE BLINKING EPISODE ON JULY 10, 2000 WAS OBJECTIVELY RECOGNIZABLE BY THE MEDICAL PROFESSION AT LARGE AS CONSTITUTING THE FIRST EVIDENCE OF VACCINE INJURY ONSET ONLY BECAUSE OF THE BENEFIT OF HINDSIGHT.

One of the reasons the Court of Appeals held that July 10, 2000 was the date to trigger the running of the statute of limitations was because of the testimony of Dr. Corbier, the Plaintiff's own expert witness. App., *infra*, 16. Again, this issue was addressed by the *Setnes* court under very similar circumstances to the case at hand.

In *Setnes*, the United States contended that Petitioner's own expert, Dr. Marks, stated that the symptoms of autism began to appear within the three-month period following the child's September 11, 1998 vaccination. *Setnes*, 57 Fed. Cl. at 130.

The Special Master relied heavily on Dr. Marks' opinion regarding the symptoms of autism appearing by December 11, 1998. However, the *Setnes* court would not base its decision on Dr. Marks' opinion. The *Setnes* court reasoned that Dr. Marks' opinion was given over two years after the child's official diagnosis, was the product of retroactive evaluation and enjoyed the benefit of hindsight. *Id.* The court further reasoned that Dr. Marks had the fully assembled puzzle in front of him, and when taking the puzzle apart, opined that the pieces he was taking apart must have come from the puzzle. Further, the court reasoned that Dr.

Marks' retroactive diagnosis is plainly inconsistent with the child's contemporaneous medical evaluation. *Id.*

In the case at hand, the Court of Appeals did not accept Petitioners' argument that Dr. Corbier's testimony should be treated the same as the *Setnes* court treated the testimony of Dr. Marks. However, the Court of Appeals concluded that it could accept Dr. Corbier's testimony with the benefit of hindsight because the case at hand did not have contemporaneous medical evaluations as occurred in *Setnes*. The rationale makes no sense. Hindsight is hindsight! The question the court must answer is whether the event of July 10, 2000 would have had any significance in Ashlyn Markovich's life had the seizure not have occurred on August 30, 2000. The event of July 10, 2000, without anything else, was a meaningless event to both the parents (subjective) and the medical community (objective). It is a piece of the puzzle of no significance without the entire puzzle being in place.

Dr. Corbier testified that eye blinking in and of itself was not sufficient to warrant a diagnosis of a seizure disorder. App., *infra*, 114. When asked his opinion if the July 10, 2000 eye blinking episode was in fact a seizure he responded by stating there were one or two possibilities. One was that the eye blinking could have either been some small seizures, subtle seizures if you will, or, two, there was a possibility that it could have been some type of brain dysfunction that started at that time, and manifesting as involuntary eye blinking. The doctor

went on to state that his answers were because of the benefit of hindsight. *Id.* at 115-116.

The standard set by the Court of Appeals is recognizable as a sign of a vaccine injury by the medical profession at large. App., *infra*, 16. Dr. Corbier's testimony certainly cannot be interpreted to conclude that eye blinking is objectively recognizable as a sign of a vaccine injury by the medical profession at large when he stated that "if a child, such as in this case, is just having eye blinking, and the child is otherwise happy and doing well, and not lethargic, it may be hard to -- unless you have a lot of training, it may be hard to even suspect necessarily that these are seizures." App., *infra*, 116.

Again, Dr. Corbier told the Special Master that hindsight was very important in the sense that because the seizures started on August 30 and looking back at the eye blinking episode you are able to relate it to be seizures. *Id.*

Dr. Corbier testified that other than eye blinking the only thing he saw in the review of the medical records as being an indicator that perhaps the event was a predecessor of epilepsy was eye blinking. Dr. Corbier did not see any mention of loss of consciousness or other additional clinical factors. *Id.* at 116-117.

With respect to the medical community at large, Dr. Corbier testified that the episode that occurred on August 30 was evidence of a seizure when he testified that most neurologists and even

general practitioners, including child pediatricians, would have described the event of August 30 as a seizure. *Id.* at 118.

Further, Dr. Corbier testified that without the seizure of August 30 occurring, based on just what happened on July 10, there would have been no conclusion or finding of a seizure disorder. *Id.* at 126.

Finally, linking the eye blinking of July 10 to the seizure disorder of August 30 was benefited by hindsight. Dr. Corbier testified, similar to the puzzle analogy in *Setnes*, that, "just looking back, I think we can look at the big picture and try to put things together." *Id.* at 126-127.

THE LOWER COURT IMPROPERLY CONCLUDED THAT THE MARKOVICHS WERE AWARE THAT ASHLYN MARKOVICH'S EYE BLINKING EPISODE OF JULY 10, 2000 WAS A SEIZURE DISORDER WELL IN ADVANCE OF THE RUNNING OF THE STATUTE OF LIMITATIONS.

The Court of Appeals concluded that the eye blinking episode began promptly after the vaccination and was connected to the injury of seizure disorder within ample time for the Markovichs to have filed a timely claim. App., *infra*, 14. The Court of Appeals referenced a January 29, 2002 report from the Mayo Clinic that the court claimed established that Mrs. Markovich understood that Ashlyn's eye blinking was seizure activity. *Id.* Appendix 91-94 and 95-102 are both reports from the

Mayo Clinic dated January 29, 2002. Those reports are significant for many reasons although establishing knowledge of any injury occurring on July 10, 2000 is not one of them. The January 29, 2002 report of Jeffrey Buchhalter, M.D., states that Ashlyn had no difficulties until first focal onset seizure occurred at four months of age. App., *infra*, 92. The report goes on to state that Ashlyn had a variety of seizures including, but not limited to, eye blinking with or without a head nod lasting seconds that can occur hundreds of times per day. *Id.*

The record in the case at hand mentions a one-time occurrence of eye blinking that occurred on July 10, 2000. Nothing in the record comes close to referencing eye blinking episodes with or without head nods lasting seconds occurring hundreds of times per day as is in the report. App., *infra*, 91-94. Further, there is nothing in the record that this information was actually relayed to Mrs. Markovich nor was there anything in the record that Mrs. Markovich had knowledge or should have had knowledge that the July 10, 2000 episode was what Dr. Buchhalter was referencing in his report of January 29, 2002.

Also, the January 29, 2002 report from the Mayo Clinic prepared by Randa G. Jarra, MBBS, App., *infra*, 95-102, references that Ashlyn was doing well during her first three and a half months of life until August 31, 2000, when she had her "*first seizure*". *Id.* at 96 (emphasis added). Dr. Jarra summarized that Ashlyn was suffering from four types of seizures of which one was repeated eye blinking, either unilateral or bilateral with or

without head nodding lasting for a few seconds and occurring hundreds of times per day. *Id.* at 96-97.

Again, there is no reasonable connection between what occurred on July 10, 2000 and what Ashlyn Markovich was suffering from as of January 29, 2002. The record was void of any reference to anything close to what was referenced in Dr. Jarra's report occurring on July 10, 2000. Also, there is nothing in the record indicating that this information was conveyed to Mrs. Markovich or that Mrs. Markovich made the connection to the event that occurred on July 10, 2000. There is no reasonable basis to conclude that because of the medical records Mr. and Mrs. Markovich were aware or should have been aware that Ashlyn Markovich suffered from an injury of some kind or had a symptom of an injury on July 10, 2000. Further, there is nothing from those medical records to indicate that the medical community at large would have concluded that the episode that occurred on July 10, 2000, without anything more, was evidence of an injury.

Finally, a September 20, 2001 report from Noran Neurological Clinic states that Mrs. Markovich advised the doctor that Ashlyn was having little seizures in the morning and that Mrs. Markovich could tell that Ashlyn was having seizures by looking at her eyes and seeing frequent eye blinking, head rolls to the side and quickly going back to center, shutting her eyes and moaning. App., *infra*, 88. The Court of Appeals concluded that this too was evidence that the Markovichs should have connected the eye blinking episode of July 10,

2000 to the injury of seizure disorder so they could have filed a more timely claim. App., *infra*, 14-16.

However, nowhere in the record was it established that on July 10, 2000, or at any time prior to August 30, 2000, was Ashlyn Markovich having frequent eye blinking, head rolls, shutting her eyes and moaning, etc. Nowhere in the record does it state that Mrs. Markovich made a connection based upon what took place on September 20, 2001 to what took place on July 10, 2000. In fact, the record is clear that what was going on after August 30, 2000 was completely different and not even close to the one meaningless event that occurred on July 10, 2000.

ALTHOUGH THE VACCINE ACT HAS BEEN INTERPRETED TO INCLUDE SUBTLE SYMPTOMS OR MANIFESTATIONS OF ONSET OF THE INJURY WITHIN THE AMBIT OF EVIDENCE THAT TRIGGERS THE RUNNING OF THE STATUTE, ASHLYN MARKOVICH'S JULY 10, 2000 EPISODE CANNOT BE INTERPRETED AS EVEN A "SUBTLE SYMPTOM".

Petitioners are well aware that the Federal Circuit has held that "the statute of limitations...begins to run upon the first symptom or manifestation of the onset of injury, even if the Petitioners reasonably would not have known at that time that the vaccine has caused an injury." *Brice*, 240 F.3d at 1373. *See also*, *Goetz*, 45 Fed. Cl. at 341-42; *Childs v. Sec'y of Health & Human Servs.*, 33 Fed. Cl. 556, 557(n)(2) (1995). However, in each of

these cases, the symptoms or the injury was clearly apparent. In *Childs*, the child suffered a febrile seizure which this court described as follows: "the child became stiff, her eyes deviated to the left, and her left arm shook for a few minutes." *Childs*, 33 Fed. Cl. at 557.

In *Brice*, the child suffered a seizure. *Brice*, 240 F.3d at 1369. In *Goetz*, the court explained that Petitioners' detailed description of the child's immediate post vaccination distress leaves no doubt that Petitioners were aware that their child had suffered an injury following one or more of the vaccinations and that "the symptoms that triggered the running of the statutes were obvious when they occurred and were never hidden..." *Goetz*, 45 Fed. Cl. at 341, 343.

As the *Setnes* court, who referenced all of the three cases, clearly stated, "it is one thing to be unaware that an obvious injury or its onset was caused by a vaccination. It is quite another to lack knowledge, through no assignable fault, of the existence of the onset. This is especially true where the treating physician does not associate the behavior as an onset of an injury." *Setnes*, 57 Fed. Cl. at 181.

THE COURT OF APPEALS' INTERPRETATION OF FIRST SYMPTOM OR MANIFESTATION OF ONSET AS IT APPLIES TO TRIGGERING THE RUNNING OF THE STATUTE OF LIMITATIONS IS CONTRARY TO THE VACCINE ACT'S OWN INTERPRETATION OF FIRST SYMPTOM OR MANIFESTATION OF ONSET AS IT APPLIES TO VACCINE INJURY TABLE CASES.

Mr. and Mrs. Markovich petitioned the United States Court of Federal Claims Office of Special Masters contending that their daughter, Ashlyn Markovich, suffered a seizure disorder and epilepsy caused in fact by the DTaP vaccine that she received on July 10, 2000. Mr. and Mrs. Markovich are not contending that the vaccination of July 10, 2000 caused a Table Injury. However, if presented as a table injury claim, the Markovichs would be able to prevail if they proved that Ashlyn manifested the first symptom of the onset of residual seizure disorder within 72 hours of her July 10, 2000 vaccination. The Court of Appeals has already decided that the eye blinking episode of July 10, 2000 was the first symptom of the residual seizure disorder. Based upon the Court of Appeals' decision, the Markovichs would prevail. However, the law does not support such a finding and, in fact, the Markovichs, based on the July 10, 2000, event would not be able to establish a table injury claim.

Bradley v. Sec'y of Dept. of Health & Human Servs., 991 F.2d 1570 (Fed. Cir. 1993) involved a child who received a DPT vaccination on January 30, 1984. *Id.* at 1571. Over the three days following the

DPT vaccination, the child had a fever of 101-104 degrees, extreme irritability, redness and swelling at the injection site, dropped head syndrome, staring episodes during which she did not react to an external stimuli and fitful sleep. *Id.* In fact, the child's mother was so concerned that she contacted a pediatrician to address the concerns. *Id.*

Ultimately, the child went on to suffer seizure disorder and was suffering from attention deficit disorder, delayed speech, aggressive behavior and head banging. The Special Master ultimately ruled that the Petitioner had "not been able to show the existence of a table injury or causation by a preponderance of the evidence". *Id.* at 1573. The Special Master reasoned that he believed the Petitioner was telling the truth as she remembered events; however, her recollections were not credible and persuasive in certain respects because there were no corroborating, contemporary medical records to support the claim and each expert's testimony conflicted as to the meaning of the events. *Id.*

In the case at hand, had the Markovichs filed a Petition claiming a table injury within 36 months of July 10, 2000, it is doubtful that they would have prevailed with their table injury claim. In the case at hand, the Court of Appeals found that one episode of sleepiness was enough to establish an onset of injury to begin the running of the statute of limitations. However, in *Bradley*, even though there were numerous concerns that were far more serious than Ashlyn Markovich blinking her eyes, the *Bradley* court did not find in favor of a table claim

because it was not based on contemporaneous medical records. *Id.*

In short, to establish an onset of injury to prove a table injury claim seems to require contemporaneous medical documentation while to determine when the statute of limitation commences, the onset of injury is established without any contemporaneous medical records or evidence of any type. Although apparently the same standard, it is being applied differently in both situations.

If the *Bradley* case was a statute of limitations claim such as the Markovichs' case, it is highly likely that the statute of limitations would have been determined to commence shortly after the vaccination. However, if the Markovich facts were substituted for the *Bradley* facts, it is extremely unlikely that a table injury would have been proven in *Bradley*. How can it be that the manifestation of the first symptom of the onset of Ashlyn Markovich's seizure disorder is sufficient to commence the running of the statute of limitations when it would be insufficient to establish a table injury claim that applies the same standard? There is no answer other than the Court of Appeals either misapplied the correct standard or applied the incorrect standard. Regardless, the decision was wrong.

CONCLUSION

The Petition for a Writ a Certiorari should be granted.

Dated: May 18, 2007

Respectfully Submitted.

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Markovich v. Secretary of Health and Human Services
C.A.Fed.,2007.

United States Court of Appeals, Federal Circuit.
Michael and Melissa MARKOVICH, Parents of Ashlyn M. Markovich, Petitioners-Appellants,
v.
SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent-Appellee.
No. 06-5039.

Feb. 20, 2007.

Background: Parents appealed from a final decision of the United States Court of Federal Claims, Susan G. Braden, J., 69 Fed.Cl. 327, affirming Special Master's report denying petition filed on behalf of daughter for compensation under the National Childhood Vaccine Injury Act.

Holding: The Court of Appeals, Linn, Circuit Judge, held that infant's eye blinking episode constituted the first symptom of a seizure disorder, rather than when infant began suffering grand-mal seizures, triggering the running of the three-year limitations period under the Vaccine Injury Act.

Affirmed.
West Headnotes
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Infant's eye blinking episode constituted the first symptom of a seizure disorder, rather than when infant began suffering grand-mal seizures, triggering the running of the' three-year limitations period under the Vaccine Injury Act; testimony confirmed that the infant's eye blinking episode, which occurred within 24-hours of vaccination, was objectively recognizable by the medical profession at large as constituting the first evidence of vaccine injury onset. National Childhood Vaccine Injury Act of 1986, § 311(a), 42 U.S.C.A. § 300aa-16(a)(2)

Mark L. Krueger, Greenhalgh Krueger & Hernandez, SC, of Baraboo, WI, argued for petitioners-appellants. Lynn E. Ricciardella, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent-appellee. With her on the brief were Peter D. Keisler, Assistant Attorney General, Timothy P. Garren, Director, Vincent J. Matanoski, Acting Deputy Director, and Catharine E. Reeves, Acting Assistant Director.

Before MICHEL, Chief Judge, RADER and LINN, Circuit Judges. LINN, Circuit Judge.

Michael and Melissa Markovich (collectively the "Markoviches") appeal from a final decision of the United States Court of Federal Claims ("Court of Federal Claims"). *Markovich* v. *Sec'y of Health & Human Servs.*, 69 Fed.Cl. 327, 336 (Fed.Cl.2005)

(*"Final Decision"*). That decision affirmed the Special Master's report, which denied the petition filed on behalf of the Markoviches' daughter, Ashlyn M. Markovich ("Ashlyn"), for compensation under the National Childhood Vaccine Injury Act ("the Vaccine Act") because it was time-barred. *See Markovich* v. *Sec'y of Health & Human Servs.*, No. 03-2015V (Fed.Cl. July 22, 2005) *("Special Master Report")*. We affirm.

I. BACKGROUND

On July 10, 2000, when she was approximately two months old, Ashlyn received a series of vaccinations, including vaccinations against diphtheria, tetanus (commonly known as lockjaw), pertussis (commonly known as whooping cough), polio, and haemophilus influenzae type B. That same day, the Maricoviches observed that Ashlyn began to rapidly blink her eyes, events that we refer to herein as the "eye blinking episodes." The Markoviches allege that, at that time, they were not concerned by the eye blinking episodes because they thought the episodes were merely an indication that Ashlyn was tired.

The eye-blinking episodes continued after July 10, 2000. On August 30, 2000, ***1355** Ashlyn became unresponsive for approximately twenty minutes, during which time all of Ashlyn's extremities jerked aggressively. The Markoviches immediately called 911. Ashlyn was taken to the Fairview Ridge Emergency Room, where she was diagnosed with having suffered a grand-mal seizure. Another seizure occurred about two weeks later, on September 14, 2000. Ashlyn continued to suffer seizures almost daily, sometimes experiencing three or more seizures

a day, including seizures documented on October 11, 14, 18, 20, 21, and 22, 2000; November 17, 2000; January 8 and 25, 2001; March 3 and 29, 2001; April 2, 3, and 17, 2001; June 8, 2001; July 10, 17, and 31, 2001; August 11 and 24, 2001; September 17, 2001; October 5 and 15, 2001; November 8, 2001; and December 7, 2001. *Final Decision*, 69 Fed.Cl. at 328-29. Ashlyn also experienced seizures that consisted of eye blinking episodes between 150 and 500 times per day. *Melissa Markovich Aff.* ¶ 7. Throughout this entire time, beginning with her hospitalization at the Fairview Ridge Emergency Room, Ashlyn was examined at several different hospitals by numerous doctors. Nevertheless, the seizures persisted.

On January 29, 2002, Ashlyn was admitted to the Mayo Clinic "to determine whether a single focus of seizure onset is likely that would be susceptible to surgical removal." *Final Decision*, 69 Fed.Cl. at 329. During that evaluation, a neurologist diagnosed Ashlyn as having experienced "four types of seizures: (1) *repeated eye blinking;* (2) clonic movement of the face, arm, and leg; (3) generalized seizures with or without focal onset; and (4) partial motor seizures." *Id.* at 330 (emphasis added). Following the evaluation, the neurologist discussed treatment options with Ms. Markovich.

On August 29, 2003, the Markoviches filed a petition for compensation under the Act, alleging that Ashlyn suffered the seizures as a result of her vaccination. On January 27, 2004, the Special Master held a status conference, indicating that an "Onset Hearing" was necessary in order to determine whether the Markoviches' petition was time-barred

as having been filed more than three years after the date on which the first symptom or manifestation of onset of the injury occurred. On November 5, 2004, the Special Master held the Onset Hearing to determine whether the onset of the seizures occurred on July 10, 2000, the date of Ashlyn's initial eye blinking episode, or on August 30, 2000, the date when Ashlyn was hospitalized and diagnosed with having a seizure.

On July 22, 2005, the Special Master found that the date of the occurrence of the first symptom or manifestation of onset of the seizures was July 10, 2000, and found that the Markoviches' petition was time-barred pursuant to 42 U.S.C. § 300aa-16(a)(2) because the petition was filed on August 29, 2003, more man three years later. *See Special Master Report*, slip op. at 24. Accordingly, the Special Master dismissed the petition for lack of jurisdiction. *Id.* The Court of Federal Claims affirmed the Special Master's decision on October 31,2005. *Final Decision*, 69 Fed.Cl. at 335-36.

The Markoviches timely appealed to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(3).

II. DISCUSSION

A. Standard of Review

Under the Vaccine Act, the Court of Federal Claims reviews the Special Master's decision to determine if it is "arbitrary, ***1356** capricious, an abuse of discretion, or otherwise not in accordance with the law." 42 U.S.C. § 300aa-l2(e)(2)(B). We effectively

review the Special Master's decision under the same standard, since we review the trial court's legal determination de novo as to whether the Special Master acted in a manner not in accordance with the law. *Althen* v. *Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1277-78 (Fed.Cir.2005) (citing *Hines* v. *Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1524 (Fed.Cir.1991)). While we owe no deference to either the Special Master or the trial court on questions of law, *Whitecotton v. Sec'y of Health & Human Servs.*, 81 F.3d 1099, 1106 (Fed.Cir.1996), we review factual findings for clear error, *Hines*, 940 F.2d at 1523.

B. Analysis

The Vaccine Act was established to increase the safety and availability of vaccines. *See* 42 U.S.C. § 300aa-l. Under the Vaccine Act, Congress established a Vaccine Injury Compensation Program through which claimants could petition to receive compensation for vaccine-related injuries. *See* § 300aa-10(a). Congress included a table in the Vaccine Act that lists injuries that may occur as a result of the administration of vaccines. *See* § 300aa-14 ("Vaccine Injury Table"). In relevant part, the Vaccine Act sets forth: In the case of... a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury.

§ 300aa-16(a)(2).

It is not disputed that the vaccines that were administered to Ashlyn are listed in the Vaccine Injury Table and that Ashlyn suffers from seizure disorders as a result of the administration of such vaccines. The question in this case is what standard should be applied in determining the date of "the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury," *id.*, and whether the eye blinking episode that occurred on July 10, 2000 meets that standard. If so, the Markoviches' petition is time-barred, having been filed more than 36 months after the July 10, 2000 episode.

The Markoviches argue that the standard for statute of limitations purposes should be a subjective one, focusing on the particular view of a specific parent. The Markoviches suggest that the limitations period was not triggered until they knew that "any injury or symptom had occurred," or "there [was] a reasonable basis of an injury that [is] separate, distinct and apart from a normal activity." *Br. for Appellant* 17-18. The Markoviches assert that the eye blinking episode that pre-dated the seizure diagnosis cannot be considered a triggering event because it was an everyday event, which they thought meant only that Ashlyn was tired. The Markoviches argue that the triggering event for statute of limitations purposes should be August 30, 2000, when, for the first time, the Markoviches became aware of an injury. The Markoviches also urge that we follow the logic of *Setnes v. United States*, 57 Fed.Cl. 175 (2003), which, according to the Markoviches, establishes that there must be a recognizable sign of a vaccine injury before

there is a manifestation *1357 of onset of injury that would trigger the statute of limitations. The Markoviches argue that, pursuant to the logic of *Setnes*, the first "manifestation of onset" (*i.e.*, the grand-mal seizure suffered on August 30, 2000), but not the first "symptom" (*i.e.*, the eye blinking episode on July 10, 2000), should start the statute of limitations because the eye blinking symptom could not reasonably alert the Markoviches that anything was wrong with Ashlyn.

The government responds that (he standard for statute of limitations purposes should be objective, focusing not on a particular parent's view but on recognized standards of the medical community. The government argues that, using an objective Standard, the Court of Federal Claims correctly held that the July 10, 2000 eye blinking episode constituted the first symptom of the seizure disorder, triggering the running of the limitations period. The government points out that the Markoviches' own expert testimony proves that the eye blinking episode constituted the onset of the seizure disorder. The government also asserts that the Markoviches' reliance on the *Setnes* decision, which is not binding on this court, is misplaced and distinguishable.

We begin our analysis with the language of the Vaccine Act, which expressly bars a petition for compensation that is filed more than 36 months after the date of the occurrence of the "first symptom or manifestation of onset" of injury. *See* 42 U.S.C. § 300aa-16(a)(2). Under the plain language of the Vaccine Act, the "first symptom or manifestation of onset" of injury means that either a "symptom" or a

"manifestation of onset" can trigger the running of the statute, whichever is first. Because Congress is presumed to have intended a disjunctive meaning by using the disjunctive word "or," we interpret the words "first symptom" and "manifestation of onset" as referring to two different forms of evidence of injury. *See, eg., Shalala* v. *Whitecotton*, 514 U.S. 268, 274, 115 S.Ct. 1477, 131 L.Ed.2d 374 (1995) (emphasizing that the Vaccine Act refers to either a "symptom" or a "manifestation of onset" and that *either* form of evidence may show the onset of the injury). This disjunctive interpretation is consistent with the use of the word "or" to distinguish the dissimilar meaning of the words "symptom" and "manifestation of onset" as used in the Vaccine Act. There is a difference between a "symptom" and "manifestation of onset." A symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury. A manifestation of onset is more self-evident of an injury and may include significant symptoms that clearly evidence an injury. For example, in this case, the eye-blinking episode was a symptom of a seizure disorder without any diagnosis, while the grand-mal seizure of August 30, 2000 was a manifestation of onset of a seizure disorder.

In *Setnes*, the Court of Federal Claims held that "where there is no clear start to the injury, such as in cases involving autism, prudence mandates that a court addressing the statute of limitations not hinge its decision on the occurrence of the first symptom." *Setnes*, 57 Fed.Cl. at 179 (internal quotation marks omitted). The Court of Federal Claims concluded

that, in cases where symptoms are hard to recognize, courts should look instead to the manifestation prong. The court in *Setnes* was concerned with the very subtle symptoms attributed with autism that can be easily confused with typical child behavior, and it distinguished the terms "symptom" *1358 and "manifestation," construing the latter as "synonymous with open, clear, visible, unmistakable, indubitable, indisputable, evident, and self-evident." *Id.* at 179-80. The *Setnes* court concluded that

in a situation such as mat before the court, where the symptoms of autism develop "insidiously over time" and the child's behavior cannot readily be connected to an injury or disorder, the court may rely on the child's medical or psychological evaluations for guidance in ascertaining when the "manifestation of onset" occurred.

Id. at 181.

A significant problem with the rationale of *Setnes* is that it effectively reads the Vaccine Act as if the statute of limitations were not triggered until there was appreciable evidence showing a symptom *and* manifestation of the injury. However, the Vaccine Act states that the statute of limitations is triggered by the "*first* symptom *or* manifestation of onset." 42 U.S.C. § 300aa-l6(a)(2) (emphasis added). The use of the words "first" and "or" require that the statute of limitations commence with whichever event (*i.e*, symptom or manifestation of onset) occurs first. The statute does not require that both events occur before the running of the limitations period can commence.

The *Setnes* construction also suggests that a subtle symptom or manifestation of onset of the injury, such as a symptom that would be recognizable to the medical profession at large but not to the parent, would not be sufficient to trigger the running of the Statute. Yet the Vaccine Act has consistently been interpreted as including subtle symptoms or manifestations of onset of the injury within the ambit of evidence that triggers the running of the statute:

Turning to the issue of accrual of the statute of limitations in Section 16(a)(2), the terms of the Vaccine Act demonstrate that Congress intended the limitations period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act. First, a particular symptom or manifestation, such as a seizure, often can result from a variety of different conditions. Hence, a petitioner typically will recognize that a particular symptom constitutes the first symptom or manifestation of the onset of a certain injury only with the benefit of hindsight, after a doctor makes a definitive diagnosis of the injury. By commencing the running of the limitations period on the date the first symptom or manifestation of the onset occurs, Congress chose to start the running of the statute before many petitioners would be able to identify, with reasonable certainty, the nature of the injury.

Brice v. *Sec'y of Health & Human Servs.*, 36 Fed.Cl. 474, 477 (1996), *aff'd on other grounds*, 240 F.3d 1367 (Fed.Cir.2001). In *Brice*, we held that equitable tolling is not available for claims arising under §

300-16(a)(2), reasoning that "the statute of limitations here begins to run upon the first symptom or manifestation of the onset of injury, even if the petitioner reasonably would not have known at that time that the vaccine had caused an injury." 240 F.3d at 1373; *see also Sharpnack v. Sec'y of Health & Human Servs.*, No. 90-983V, 1992 WL 167255, at *2 (Cl.Ct. Special Master June 29, 1992), *aff'd*, 27 Fed.Cl. 457 (1993), *aff'd*, 17 F.3d 1442 (Fed.Cir.1994) (table) (holding that "in many Vaccine Program cases the injuries are first manifested ***1359** as subtle signs and seizures of less complicated nature, e.g., seizures lasting less than 30 minutes or seizure activity so subtle as to be unrecognized at their onset").

The Supreme Court, in *Whitecotton*, interpreted the terms "first symptom or manifestation of onset," as that language is used in §§ 300aa-ll(c)(l)(C)(i) [FN1] and 300aal4(a) [FN2] of the Act, to include subtle symptoms. Although these sections deal with causation and the temporal relationship of the administration of the vaccine and evidence of injury, the relevant language of those sections is virtually identical to the relevant language of § 300aa-l6(a)(2) at issue in this case. In *Whitecotton*, the Court emphasized that the proper focus is on the first evidence of injury, emphasizing that *any* observable "symptom or manifestation" may be the first evidence of injury. 514 U.S. at 274, 115 S.Ct. 1477. The Supreme Court, unlike the Court of Federal Claims in *Setnes*, did not require that a petitioner appreciate the significance of that evidence. Notably, while the Markoviches contend that the July 10, 2000 eye blinking episode did not start the running of the statute of limitations, they

argue that it supports causation, reasoning that "[a]lthough petitioners' experts are using that event [eye blinking on July 10, 2000] to support their opinion that the seizure disorder that manifested itself on August 30, 2000, was caused by the vaccination of July 10, 2000, it should not be used against petitioners to support the respondent's argument that the statute of limitations began to run on July 10, 2000." The statutory language of the causation provision is the same as the statute of limitations provision. There is no principled basis to conclude that "first symptom or manifestation of onset" should be construed one way for causation and another way for the statute of limitations.

FN1. § 300aa-11(c)(l)(C)(i) provides:
A petition for compensation under the Program for a vaccine-related injury or death shall contain ... an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine ... and the *first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death* occurred within the time period... in the Vaccine Injury Table. 42 U.S.C. § 300aa-ll(c)(l)(C)(i) (emphasis added).

FN2. § 300aa-14(a) provides:
The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and

> deaths resulting from the administration of such vaccines, and the time period in which the *first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths* is to occur after vaccine administration for purposes of receiving compensation under the Program....
> 42 U.S.C. § 300aa-14(a) (emphasis added).

Setnes is also factually distinguishable from the Markoviches' case. The eye blinking episodes here were not so readily confused with typical child behavior over the course of the limitations period as were the symptoms of autism in *Setnes*. The eye blinking episodes in this case began promptly after the vaccination and were connected to the injury of seizure disorder within ample time to have filed a timely claim. As discussed above, the January 29, 2002 report from the Mayo Clinic established that "repeated eye-blinking" was not only a symptom of seizure activity but also manifested one type of seizure activity. The record also reflects that, as ***1360** of September 20, 2001, Ms. Markovich understood that Ashlyn's eye blinking was seizure activity. *See Special Master Report*, slip op. at 4. Moreover, the Markoviches' own medical expert, Dr. Corbier, testified at the Onset Hearing that:

> [T]he eye blinking could have either been some small seizures, subtle seizures if you will, or there is also the possibility that it could have been some type of brain dysfunction.
>
> There is no question that [when the eye blinking episode occurred] there was a mild seizure....

[T]here was some type of dysfunction of some sort that likely started on July 10th, leading to a documented seizure on August 30th.

Similarly, Dr. Corbier's expert report states that "the patient's onset of possible seizures (paroxysms of rapid eye blinking) ... occurred within 24 hours following a set of immunizations...." Thus, as distinguished from *Setnes*, the eye blinking episodes were not normal child behavior, were part of the same injury that culminated on August 30, 2000 in a grand-mal seizure, and would have at the very least raised Dr. Corbier's suspicions.

We have previously explained that the Vaccine Act's statute of limitations must be strictly and narrowly construed because it is "a condition on the waiver of sovereign immunity by the United States, and courts should be careful not to interpret [a waiver] in a manner that would extend the waiver beyond that which Congress intended." *Brice*, 240 F.3d at 1370. A subjective standard that focuses on the parent's view would result in an uneven and perhaps overly broad application of the statute of limitations dependent entirely on the subjective perceptions of lay persons having widely varying degrees of medical awareness or training. On the other hand, an objective standard that focuses on the recognized standards of the medical profession at large treats petitioners equally, without regard to their individual degree of medical awareness. An objective standard is consistent with the statutory requirement that the *first* symptom *or* manifestation of onset of the injury begins the running of the statute of limitations, as well as the cases discussed

supra that have consistently construed the Vaccine Act to include subtle symptoms that would be recognizable to the medical profession at large but not necessarily to the parent. *See generally Goetz v. Sec'y Health & Human Servs.*, 45 Fed.Cl. 340, 342 (1999) (following *Brice* and holding that a vaccine claim is based on "the occurrence of an event recognizable as a sign of a vaccine injury *by the medical profession at large*, not the diagnosis that actually confirms such an injury in a specific case" (emphasis added)), *aff'd*, 4 Fed.Appx. 827 (Fed.Cir.2001).

For all of the reasons discussed above, we hold that "the first symptom or manifestation of onset," for the purposes of § 300aa-16(a)(2), is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large. Because the testimony of Dr. Corbier and others confirms that Ashlyn's eye blinking episode on July 10, 2000 was objectively recognizable by the medical profession at large as constituting the first evidence of vaccine injury onset, *i.e.*, the first symptom of injury, and because the Markoviches filed their petition on August 29, 2003, more than 36 months after the initial symptoms, the petition is time-barred under § 300aa-16(a)(2).

CONCLUSION

For the foregoing reasons, the *Final Decision* is

AFFIRMED.

*1361 COSTS

No costs.

C.A.Fed.,2007.
Markovich v. Secretary of Health and Human Services
477 F.3d 1353

END OF DOCUMENT

Markovich ex rel. Markovich v. Secretary of Dept. of Health and Human Services
Fed.Cl.,2005.

United States Court of Federal Claims.
Michael and Melissa MARKOVICH, parents of Ashlyn M. Markovich, Petitioners,
v.
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.
No. 03-2015V.

Oct. 31,2005.

Background: Parents filed a petition for compensation under the National Childhood Vaccine Injury Act, alleging that their child's seizure disorder and intractable epilepsy were caused by diphtheria, tetanus, and acellular pertussis (DTaP), inactivated polio virus (IPV), and haemophilus influenzae type B (Hib) vaccines that child received on July 10, 2000. The special master ruled that petition was untimely, and parents filed motion for review.

Holdings: The Court of Federal Claims, Braden, J., held that:

(1) special master's finding that July 10, 2000 was the date of the "first symptom or manifestation of onset" of seizure disorder for statute of limitations purposes was not arbitrary or capricious,
(2) and special master did not abuse her discretion in relying on expert testimony based on "hindsight" to find that onset date of child's seizure disorder for

statute of limitations purposes was date of vaccinations when child had repeated eye blinking episode.

Motion denied.

West Headnotes

[1] Health 198H 389

198H Health
198HII Public Health
198Hk383 Contagious and Infectious Diseases

198Hk389 k. Vaccine Injury Programs; Government Liability. Most Cited Cases

Special master's finding in vaccine injury case that July 10, 2000 was the date of the "first symptom or manifestation of onset" of seizure disorder for statute of limitations purposes was not arbitrary or capricious; finding was based on testimony of petitioners' expert that child's eye blinking episode on July 10, 2000, which was the date of vaccinations, was first objective symptom of seizure disorder. Public Health Service Act, § 2116(a)(2), 42 U.S.C.A. § 300aa-16(a)(2).

[2] Health 198H 389

198H Health
198HII Public Health
198Hk383 Contagious and Infectious Diseases
198Hk389 k. Vaccine Injury Programs; Government Liability. Most Cited Cases

Special master in vaccine injury case did not abuse her discretion in relying on expert testimony based on "hindsight" to find that onset date of child's

seizure disorder for statute of limitations purposes was date of vaccinations when child had repeated eye blinking episode. Public Health Service Act, § 2116(a)(2), 42 U.S.C.A. § 300aa-16(a)(2).

[3] Health 198H 389

198H Health
198HII Public Health
198Hk383 Contagious and Infectious Diseases
198Hk389 k. Vaccine Injury Programs;

Government Liability- Most Cited Cases
Statute of limitations on claims under the National Childhood Vaccine Injury Act begins to run from the first symptom or manifestation of the onset of injury, even if a petitioner reasonably would not have known at the time that the vaccine had caused an injury. Public Health Service Act, § 2116(a)(2), 42 U.S.C.A. § 300aa-16(a)(2).

***327** Mark L. Krueger, Greenhalgh Krueger Hernandez & Fasi, S.C., Baraboo, Wisconsin, for Petitioners.
Traci R. Patton, United States Department of Justice, Washington, D.C., for Respondent.

MEMORANDUM OPINION

BRADEN, Judge.
On July 22, 2005, a Special Master of the United States Court of Federal Claims ("the Special Master") issued an unpublished decision finding that Petitioners did not file a ***328** claim for relief under the National Childhood Vaccine Injury Act, 42

U.S.C. §§ 300aa-l to -34 (2000 & Supp. II 2003), ("Vaccine Act") within the three-year statute of limitations and, therefore, the United States Court of Federal Claims did not have jurisdiction to reach the merits of this case. *See Markovich v. Sec'y Dep't of Health & Human Servs.*, No. 03-2015V, slip op. (Fcd.Cl.Spec.Mstr. July 22, 2005) ("*Markovich*").

On August 19, 2005, Petitioners filed a Motion for Review challenging the Special Master's decision. On September 19, 2005, the Government filed a Response. The court has issued this Memorandum Opinion on an expedited basis to facilitate any appellate review that Petitioners may decide to pursue.

RELEVANT FACTS[FN1]

> FN1. The relevant facts recited herein are summarized from factual findings found in *Markovich*, at 1-13. Citations to the record are noted as follows: "Pet. ¶ ___" refers to the August 29, 2003 Petition; "Pet Ex. ___ at ___" refers to Petitioners' exhibits; "Aff. ¶ ___" refers to the Affidavit of Melissa Markovich; and "TR at ___" refers to the transcript of the November 5, 2004 hearing before the Special Master.

Ashlyn Markovich ("Ashlyn") was born on May 12, 2000 to Melissa and Michael Markovich. *See Markovich*, at 4 (Pet. Ex. 1 at 1). On July 10, 2000, Ashlyn received Diphtheria, Tetanus, and Acellular Pertussis ("DtaP"), Inactivated Polio Virus ("IPV"), and *Haemophilus influenzae* type B ("Hib")

vaccinations. *Id.* at 1. On July 10, 2000, Ashlyn also experienced a repeated eye blinking episode.[FN2] *Id.* at 2, 14 (Pet ¶ 3; Aff. ¶ 4). Ashlyn's eye blinking episodes continued until August 30, 2000, when she was admitted to Fairview Ridges Hospital in Burnsville, Minnesota ("Fairview Ridges Hospital") and diagnosed with a seizure, but the cause was not identified. *Id.* at 2-3, 5 (Pet Ex. 18 at 5; Pet Ex. 14 at 30).

> FN2. Ashlyn's parents noticed the repeated eye blinking, but assumed that she was tired. *See Markovich*, at 2, 14 (Pet. ¶ 3; Aff. ¶ 4).

On September 8, 2000, Ashlyn had a routine examination, during which her pediatrician, Dr. Tiffani Mullins, was advised of Ashlyn's seizure, but, nevertheless, found Ashlyn normal. *Id.* at 5 (Pet. Ex. 4 at 5). On September 14, October 11, 14, 18, 20, 21, and 22, 2000, however, Ashlyn experienced other seizures. *Id.*

On October 16, 2000, Dr. Ronald H. Spiegel, a Pediatric Neurologist at St. Paul Children's Hospital in St. Paul, Minnesota ("Children's Hospital"), examined Ashlyn and prescribed Tegretol, an antiseizure medication, which she began taking on October 21, 2000. *Id.* (Pet. Ex. 6 at 210; Pet Ex. 16 at 45-46). On October 22, 2000, Ashlyn again was admitted to Children's Hospital, at which time the Tegretol was discontinued and another series of tests was performed. *Id.* at 5 (Pet. Ex. 6 at 159-63). On November 9, 2000, Ashlyn had a follow-up examination with Dr. Spiegel. *Id.* at 6 (Pet. *Ex.* 16 at 44). On November 17, 2000, Ashlyn experienced

another seizure and again was taken to Fairview Ridges Hospital. *Id.* (Pet Ex. 14 at 23-26; Pet. Ex. 18 at 12). She was treated and discharged on November 20, 2000. *Id.* (Pet. Ex. 16 at 4-5).

On January 8, 2001, Ashlyn returned to Fairview Ridges Hospital and was diagnosed as having experienced a seizure. *Id.* (Pet. Ex. 14 at 17-19). After two to three weeks of coughing, congestion, and fevers, Ashlyn was examined by Dr. Mullins on January 25, 2001. *Id.* (Pet. Ex. 4 at 9). Ashlyn was diagnosed with a prolonged upper respiratory infection and probable acute bronchitis. *Id.* Later that same day, however, Ashlyn again was admitted to Fairview Ridges Hospital and diagnosed as having experienced a seizure. *Id.* (Pet. Ex. 14 at 14-16). On January 29, 2001, Ashlyn had a follow-up visit with Dr. Spiegel, who reported that Ashlyn was developing well, notwithstanding the seizure episodes. *Id.* (Pet. Ex. 16 at 41-42).

On March 3, 29, April 2, 3, 17, June 8, and July 10, 2001, Ashlyn experienced additional seizures. *Id.* at 6-7 (Pet. Ex. 5 at 89-91, 99-100; Pet. Ex. 6 at 210; Pet. Ex. 14 at 4-7; Pet. Ex. 18 at 19; Pet. Ex. 19 at 2). Following the July 10, 2001 seizure, Ashlyn was admitted to St Francis Regional Medical Center, in Shakopee, Minnesota ("St. Francis"), ***329** and underwent blood tests that indicated a mildly elevated white blood cell count. *Id.* at 7 (Pet. Ex. 5 at 90-91). Ashlyn was discharged on that date, against medical advice. *Id.* (Pet. Ex. 5 at 91).

On July 12, 2001, Ashlyn received a neurological assessment from Dr. Steven Janousek of the Noran

Neurological Clinic, in Minneapolis, Minnesota. *Id.* (Pet Ex. 7 at 71-72). From July 18, 2001 to April 26, 2002, Ashlyn's mother frequently contacted Dr. Janousek to advise him of Ashlyn's condition and request advice about seizure management. *Id.* (Pet. Ex. 7). On July 23, 2001, Ashlyn had a urine analysis that indicated that her organic acid pattern screen was not consistent with that of a known excess of acid, her urine amino acid pattern was not consistent with a known disorder of amino acid metabolism, but an oligosaccharides screen was normal. *Id.* at 7-8 (Pet. Ex. 5 at 34-36).

On July 17, 31, August 11, and 24, 2001, Ashlyn experienced additional seizures. *Id.* at 7-8 (Pet. Ex. 5 at 31-32, 85-88, 92-93, 97; Pet. Ex. 18 at 31). On August 28, 2001, Ashlyn was re-examined by Dr. Janousek. *Id.* at 8 (Pet. Ex. 7 at 58). On September 10, 2001, Ashlyn was admitted to the Pediatric Epilepsy Ward at Children's Hospital to start a ketogenic diet [FN3] *Id.* (Pet. Ex. 6 at 202-206, 209-213, 216). During this time, Ashlyn also was evaluated by the Speech Pathology Department, which determined that Ashlyn had a mild receptive and expressive language delay. *Id.* (Pet. Ex. 6 at 89).

> FN3. A ketogenic diet is a:
> stringent, mathematically calculated diet high in fat and low in protein and carbohydrates that, when followed conscientiously, produces a by-product called ketones in patients' blood and urine.
>
> High concentrations of ketones in the body control the frequency and severity of a seizures, although the biochemical

> mechanisms for this phenomenon are not yet known.
> The Ketogenic Diet, *The Epilepsy & Brain Mapping Program*, *at* http://www.epipro.com/k_diet.html (last visited October 31, 2005) (cited by *Markovich*, at 8 n.19).

On September 13, 2001, Ashlyn was discharged from Children's Hospital, but on September 17, October 5, 15, and November 8, 2001, Ashlyn experienced additional seizures and was taken to St Francis. *Id.* at 8-9 (Pet. Ex. 6 at 202-205; Pet. Ex. 5 at 79-84; Pet. Ex. 18 at 24).

On December 7, 2001, Ashlyn was taken to St Francis, where her mother observed a cluster of seizure activity. *Id.* at 9 (Pet. Ex. 5 at 75-76). Later that afternoon, Ashlyn again was taken to the hospital with seizure activity. *Id.* Shortly after her second discharge, Ashlyn returned with a recurrence of seizure activity. *Id.*

On December 26, 2001, Ashlyn was admitted to Children's Hospital for a prolonged evaluation. *Id.* to St. Francis. *Id.* (Pet. Ex. 5 at 48-49). After being released, Ashlyn experienced a one-and-a-half hour seizure that her mother promptly reported to the hospital. *Id.* (Pet. Ex. 6 at 5).

On October 8, 2002, Ashlyn was examined to prepare for the implantation of a VNS. *Id.* (Pet. Ex. 6 at 181-184). On October 10, 2002, Dr. Mary E. Dunn implanted the VNS. *Id.* (Pet. Ex. 6 at 178-180). In the months following the implantation, however,

there was little to no improvement in seizure frequency and intensity. *Id.* (Pet. Ex. at 6 at 165-171).

On January 3, 2002, Ashlyn received a speech and language evaluation by Ms. Michelle Laurent at St. Francis Rehabilitative Service. *Id.* (Pet. Ex. 5 at 43-45). After observing significant speech and language delays, Ms. Laurent recommended that Ashlyn receive therapy for slow development. *Id.* (Pet. Ex. 5 at 44).

On February 2, April 25, and June 19, 2003, Ashlyn experienced additional seizures. *Id.* at 12-13 (Pet. Ex. 5 at 37-42).

PROCEDURAL BACKGROUND

On August 29, 2003, Michael and Melissa Markovich, the parents of Ashlyn Markovich, ("Petitioners") filed a Petition for Compensation under the Vaccine Act ("the Petition"), alleging that Ashlyn's seizure disorder and intractable epilepsy were caused by the DtaP, IPV, and/or HiB vaccines that Ashlyn received on July 10, 2000. *Id.* at 2. In support, Petitioners submitted Ashlyn's medical records, Ms. Markovich's Affidavit ("the Markovich Affidavit"), expert Affidavits of Dr. Frank J. Ritter (Pet. Ex. 12) and Dr. Donald H. Marks (Pet. Ex. 17), and an expert report from Dr. Jean-Ronel Corbier (Pet. Ex. 20).

At a January 27, 2004 status conference, the Special Master indicated that an Onset Hearing with expert testimony was necessary, because the Petition and

the Markovich Affidavit raised statute of limitations concerns. *See Markovich*, at 4; *see also* Pet. ¶ 3; Aff. ¶ 4. On June 2, 2004, Petitioners filed the expert report of Dr. Corbier, a Pediatric Neurologist. *See Markovich*, at 4. On November 5, 2004, the Special Master conducted an Onset Hearing in Washington, D.C., at which Dr. Corbier testified. *Id.* The Government declined to proffer an expert witness to interpret the significance of Ashlyn's ***331** July 10, 2000 and subsequent eye blinking episodes. *Id.*

On July 22, 2005, the Special Master issued a decision finding that the first symptom or manifestation of onset of Ashlyn's seizure disorder occurred on July 10, 2000, the date of her vaccinations and on which she had an initial eye blinking episode. Since Petitioners filed their claim on August 29, 2003, fifty days after the three-year limitations period expired, however, the Special Master ruled that the United States Court of Federal Claims did not have jurisdiction to consider the merits of the Petition. *Id.* at 2.

On August 19, 2005, Petitioners timely filed a Motion for Review of the Special Master's July 22, 2005 decision, pursuant to Appendix B, Rule 23 of the United States Court of Federal Claims. Therein, Petitioners assert that their claim was filed within the 36-month limitations period, because the limitations period did not commence until August 30, 2000, the date that Ashlyn first was diagnosed by a licensed physician as having experienced a seizure. Petitioners contend that the Special Master incorrectly interpreted Dr. Corbier's expert opinion to fix with certainty the July 10, 2000 repeated eye

blinking episode as the onset of Ashlyn's seizure disorder. *See* Pet Mem. of Objections at 1-2. Petitioners also contend that the July 10, 2000 repeated eye blinking episode was not a "symptom" of a seizure disorder and that the Special Master erred in relying on "hindsight." *Id.* at 2-4. In addition, Petitioners take issue with the Special Master's gratuitous remark that if this case were allowed to proceed it would "*open the door to illegitimate claims.*" *Id.* at 4-5 (emphasis added). Finally, Petitioners argue that the Special Master misconstrued *Brice v. Sec'y Health & Human Servs.*, 240 F.3d 1367 (Fed.Cir.2001); *Goetz* v. *Sec'y Health & Human Servs.*, 45 Fed.Cl. 340 (Fed.Cl.1999), *aff'd*, 4 Fed. App'x. 827 (Fed.Cir.2001); and *Childs* v. *Sec'y Health & Human Servs.*, 33 Fed.Cl. 556 (Fed.Cl.1995). *Id.* at 5-6.

On September 19, 2005, the Government filed a Response. Accordingly, these issues are now ripe for review by the United States Court of Federal Claims. *See* 42 U.S.C. § 300aa-12(e).

DISCUSSION

A. Standard Of Review.

Congress requires that the United States Court of Federal Claims analyze conclusions of law made by a Special Master under the Vaccine Act *de novo*, *i.e.*, pursuant to a "not in accordance with law" standard. *See* 42 U.S.C. § 300aa-12(e)(2)(B); *see also Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1277 (Fed.Cir.2005) ("Under the Vaccine Act, the [United States] Court of Federal Claims reviews the

special master's decision to determine if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.") (internal quotations omitted). The "not in accordance with law" standard is applicable where there is dispute over statutory construction or other legal issues. *See Saunders* v. *Sec'y Dep't of Health & Human Servs.*, 25 F.3d 1031, 1033 (Fed.Cir.1994) (quoting *Munn v. Sec'y Dep't of Health & Human Servs.*, 970 F.2d 863, 870 n. 10 (Fed.Cir.1992)); *Hines* v. *Sec'y Dep't of Health & Human Servs.*, 940 F.2d 1518, 1527(Fed.Cir.1991).

Factual findings of a Special Master should not be set aside unless they are held to be arbitrary and capricious or a Special Master has acted in a manner evidencing an abuse of discretion. *See* 42 U.S.C. § 300aa-12(e)(2)(B); *see also Turner v. Sec'y of Health & Human Servs.*, 268 F.3d 1334, 1337 (Fed.Cir.2001). The United States Court of Appeals for the Federal Circuit, recognizing that "no uniform definition of this standard has emerged," has instructed the court that the decision of a Special Master may be found to be "arbitrary and capricious," but only if there has been reliance: on factors which Congress has not intended [the special masters] to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence ... or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Hines, 940 F.2d at 1527 (quoting ***332** *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463

U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983)) (discussing a similar standard of review for agency rulemaking under the Administrative Procedure Act).

Discretionary rulings are reviewed under an "abuse of discretion standard." *Munn*, 970 F.2d at 870 n. 10; *see also Turner*, 268 F.3d at 1337.

B. The Relevant Statute Of Limitations.

For vaccines listed in the Vaccine Injury Table [FN8] and administered after October 1, 1988 ("post-Act"), the Vaccine Act provides:

> FN8. The DTaP, IPV, and Hib vaccinations are listed on the Vaccine Injury Table. *See* 42 C.F.R. § 100.3(a) (2005).

> [I]f a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months *after the date of the occurrence of the first symptom or manifestation of onset* or of the significant aggravation of such injury.

42 U.S.C. § 300aa-16(a)(2) (emphasis added). The starting point for a statute of limitations analysis, therefore, requires identification of the date of the occurrence of either (a) the first symptom or (b) manifestation of onset or of the significant aggravation of such injury.[FN9] *Id.; see also Shalala v. Whitecotton*, 514 U.S. 268, 274, 115 S.Ct. 1477, 131 L.Ed.2d 374 (1995) ("[T]he symptom or

manifestation occurring after the vaccination must be evidence of the table injury's onset[.]")-

> FN9- "The term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4).

Since the Vaccine Act's statute of limitations is an explicit condition of the waiver of sovereign immunity by the United States, the United States Court of Appeals for the Federal Circuit has instructed the court to be "careful not to interpret a waiver in a manner that would extend the waiver ... beyond that which Congress intended." *Brice*. 240 F.3d at 1370 (quoting *Stone Container Corp. v. United States*, 229 F.3d 1345, 1352 (Fed.Cir.2000) (internal quotation omitted)). Our appellate court also has clarified that equitable tolling is not available for claims arising under the Vaccine Act. *See Brice*, 240 F.3d at 1374 (holding that equitable tolling is not available in post-Act cases and explaining that it is "inconsistent with the existing statutory scheme"); *see also Weddel v. Sec'y of Health & Human Servs.*, 100 F.3d 929, 931-932 (Fed.Cir.1996) (holding that equitable tolling is not available in pre-Act cases).

C. The Court's Resolution Of Petitioners' Motion For Review.

1. The Special Master's Finding That July 10, 2000 Was The Date Of The "First Symptom Or Manifestation Of Onset" Is Not Arbitrary Or Capricious.

[1] Petitioners challenge the Special Master's determination that Dr. Corbier concluded that Ashlyn's July 10, 2000 repeated eye blinking episode was the onset of a seizure disorder. *See* Pet. Mem. of Objections at 1-2. Petitioners argue that "Dr. Corbier testified that it was his opinion that the onset date of Ashlyn's seizure disorder was August 30, 2000." *Id.* at 1 (citing TR at 9). The court disagrees.

The court presumes that Petitioners' argument is based on Dr. Corbier's testimony that "on August 30th, 2000, the patient had a generalized tonic-clonic seizure that lasted at least 20 minutes. So as of that date, the patient did definitively have documented seizures and that went beyond August 30th, 2000." TR at 9. To interpret this as an opinion that the onset of Ashlyn's seizure disorder was August 30, 2000 misconstrues Dr. Corbier's testimony, particularly when viewed in its entirety. For example, Dr. Corbier testified that Ashlyn's July 10, 2000 eye blinking episode was the result of a cerebral dysfunction and is "linked to" the August 30, 2000 seizure. *See* TR at 10. Dr. Corbier also testified that, in his professional judgment, July 10, 2000 was the "time line of when something first started [that] may have [precipitated the July] 10th [incident] ... was due to some type of cerebral

dysfunction, and then the results culminated in her ***333** having a seizure ... on August 30th." [FN10] *Id.* And, as Dr. Corbier explained:

> FN10. Dr. Corbier initially misstated the date of the repeated eye blinking episode, but corrected the record to identify the correct date, July 10,2000. *See* TR at 10.

In terms of timing, it appears like there was some type of precipitating event in this case with the vaccine and on that same day you have the eye blinking episodes, irregardless of whether the eye blinking turned out to be some type of cerebral dysfunction or little seizure ... [a]nd that they progressed on August 30th to a full-blown seizure. *Id.* at 14.

In addition, Dr. Corbier explained that Ashlyn's July 10, 2000 eye blinking episode was an "objective symptom" of a seizure disorder.[FN11] *Id.* at 19, 25. Moreover, in response to the Special Master's question at the Onset Hearing about whether "the first symptom occurred with the eye blinking episodes that were noted on July 10th[,]" Dr. Corbier responded affirmatively: "Yes, I think there was some type of dysfunction of some sort that likely started on July 10th, leading to a documented seizure." *Id.* at 19. Later in his testimony, Dr. Corbier advised the Special Master that "the eye fluttering and seizure disorder are both symptoms of a single process caused by an insult to the brain at about the time of the vaccinations." *Id.* at 25. Accordingly, the Special Master correctly concluded that: "Dr. Corbier made clear that even though he

could not have said with absolute certainty on July 10, 2000, that Ashlyn had a seizure disorder, he was able to testify that problematic neurological symptoms were present." *Markovich*, at 19.

> FN11. Petitioners contend that the repeated eye blinking episode is not a "symptom" of Ashlyn's seizure disorder. *See* Pet. Mem. of Objections at 2-3. Petitioners define a "symptom" as "any subjective evidence of a disease or of a patient's condition" and argue that the eye blinking episode was neither subjective evidence nor objective evidence of a neurological disorder, disease, or condition. *Id.* (quoting Dorland's). As discussed herein, the court is bound by this precedent, not a medical dictionary. See *infra* Discussion, Part (C)(3), at 10-11.

For these reasons, the court has determined that the Special Master's finding that the date of the onset was July 10, 2000 was not arbitrary or capricious.[FN12]

> FN12. Petitioners also object to the Special Master's statement that:
> [P]etitioners need not understand the significance of a first symptom, the symptom merely must be manifest. To hold otherwise would open the door to many who would conveniently argue that while they observed certain activity shortly after vaccination that was explained to be the first symptom or manifestation of an onset of an injury, because they lack medical training, they failed to

recognize those first symptoms as the manifestation of an injury.

See Pet. Mem. of Objections at 4-5 (referencing *Markovich*, at 23). Although this statement was entirely gratuitous and not justified by any evidence in the record, the court holds that it is not grounds for reversal. *See Turner*, 268 F.3d at 1337.

2. The Special Master Did Not Abase Her Discretion In Relying On Expert Testimony Based On "Hindsight."

[2] At the Onset Hearing, Dr. Corbier acknowledged that "hindsight is very important, in the sense that... the full-fledged seizures started on August 30th, and *looking back* ... the eye blinking episodes had been seizures." TR at 12-13, 23 (emphasis added). Petitioners take issue with the Special Master's reliance on Dr. Corbier's opinion for this reason. *See* Pet. Mem. of Objections at 3-4; *see also* TR at 12-13, 23.

The court has not identified any text in the Vaccine Act or decisions of the United States Court of Appeals for the Federal Circuit that address this issue, although the United States Court of Federal Claims has directly considered this evidentiary consideration from different perspectives. *Compare Brice v. Sec'y Dep't of Health & Human Servs.*, 36 Fed.Cl. 474, 477 (Fed.Cl.1996) (observing, without citation, that Congress was aware that "a petitioner typically will recognize that a particular symptom constitutes the first symptom or manifestation of the onset of a certain injury only with the benefit of

hindsight, after a doctor makes a definitive diagnosis of the injury") *with Setnes v. United States*, 57 Fed.Cl. 175, 180 (Fed.Cl.2003) (criticizing a Special Master's reliance on an expert's opinion that was "the product of a ***334** retroactive evaluation and enjoyed the benefit of hindsight," because the expert "had the fully assembled puzzle in front of him, and when taking the puzzle apart, opined that the pieces he was taking apart must have come from the puzzle").

The *Setnes* court was particularly concerned with the expert's hindsight diagnosis because it was "plainly inconsistent with ... contemporaneous medical evaluations." *Setnes*, 57 Fed.Cl. at 180. Unlike *Setnes*, the record in this case does not include any contemporaneous medical evaluations of Ashlyn between July 10, 2000 and August 30, 2000. Accordingly, the court determines that the Special Master did not abuse her discretion in relying on Dr. Corbier's conclusions, notwithstanding the benefit of "hindsight."

3. As A Matter Of Law, The Statute Of Limitations Runs From The First Symptom Or Manifestation Of The Onset, "Even If A Petitioner Reasonably Would Not Have Known At The Time That The Vaccine Had Caused An Injury."

[3] In the alternative, Petitioners argue that the repeated eye blinking episode on July 10, 2000 cannot be interpreted as the onset of Ashlyn's seizure disorder, because they "were never of the opinion that the eye blinking was anything other

than their child being tired." Pet Mem. of Objections at 2.

The United States Court of Appeals for the Federal Circuit, however, has held that the statute of limitations in Vaccine Act cases "begins to run upon the first symptom or manifestation of the onset of injury, even if the petitioner reasonably would not have known at the time that the vaccine had caused an injury." *Brice*, 240 F.3d at 1373; *see also Goetz* v. *Sec'y of Health & Human Servs.*, 45 Fed.Cl. 340, 341 (Fed.Cl.1999) ("[I]t is clear that Congress intended the cause of action in a Vaccine Injury Table case to accrue upon occurrence of the first symptom of an injury, not upon the first identification of a link between the injury and the vaccination."). Because applicable precedent does not require that a petitioner appreciate or recognize that a symptom or manifestation of the onset was caused by a vaccine, but only that the symptom or manifestation occur, the Special Master was correct in finding that:

It is not relevant to the onset query that the parents were unaware that the blinking episodes were a neurological symptom that served as the precursor to the seizure that Ashlyn would experience on August 30, 2000. What is relevant to the present discussion is that the parents were aware that the blinking episodes began on July 10, 2000, and continued until the August 30, 2000 seizure.

Markovich, at 17-18.

Petitioners counter that, "although factually dissimilar[,]" the rationale in *Setnes* should govern in this case. Pet. Mem. of Objections at 3-4. The

Setnes court held that the onset of a petitioner's autism was not the date that the petitioner began exhibiting behavior consistent with autism, *e.g.*, temper tantrums, staring, but instead, the date on which the petitioner's autism "became evident." *Setnes*, 57 Fed.Cl. at 181. In determining that the statute of limitations should not begin to run prior to a medical diagnosis, the United States Court of Federal Claims remanded that case to the Special Master and explained:

As distinguished from other medical conditions, ... the beginning stage of autism cannot be reduced to a single, identifiable symptom. Many of the initial 'symptoms' are subtle and can easily be confused with typical child behavior. Where there is no clear start to the injury, such as in cases involving autism, prudence mandates that a court addressing the statute of limitations not hinge its decision on the 'occurrence of the first symptom.'

Id. at 179 (citations omitted).[FN13]

> FN13. The United States Court of Appeals for the Federal Circuit has not had an occasion to review *Setnes*, because the case has been stayed pending a decision on causation. *See Autism, General Order # 1*, 2002 WL 31696785, 2002 U.S. Claims LEXIS 365 (Fed.Cl.Spec.Mstr. July 3, 2002).

Although the *Setnes* decision concerned autism, it suggested an interpretation of the Vaccine Act statute of limitations that was *335 faithful to precedent, but also recognized the important need for the requisite medical certainty to trigger the

statute of limitations, particularly in cases involving children. *Id.; see also Brice*, 240 F.3d at 1376 (Newman, J., dissenting) (warning that a rigid approach to the statute of limitations "defeats the Act's purpose to provide a non-adversarial and equitable governmental response to vaccine-related injury"); Katherine Marie Bulfer, Comment, *Childhood Vaccinations And Autism: Does The National Childhood Vaccine Injury Act Leave Parents Of Children With Autism Out In The Cold With Nowhere To Go?*, 27 Campbell L. Rev. 91, 101 (2004) (endorsing the *Setnes* court's concern with subtle symptoms and suggesting that more weight be accorded to contemporary medical evaluations).

The court is persuaded by the logic of *Setnes* and suggests, if the United States Court of Appeals for the Federal Circuit has occasion to review the instant decision, that a more definitive and equitable manner of determining the time certain for the commencement of the statute of limitations be considered, by modifying *Brice* as follows: "in Vaccine Act cases, the statute of limitations begins to run upon identification of the first symptom or manifestation of the onset of injury [by a licensed physician]." FN14

> FN14. In recent years, Congress has considered amendments to the Vaccine Act, including an extension of the limitation periods. *See, e.g.*, H.R. 1297, 109th Cong., at Sec. 7 (2005) (extending the statute of limitations to six years and permitting petitions previously dismissed as being

untimely to be re-filed within two years); H.R. 1349, 108th Cong., at Sec. 7 (2003) (same).

4. The Special Master Did Not Misconstrue Applicable Precedent.

Finally, Petitioners argue that the Special Master incorrectly relied on *Brice*, 240 F.3d 1367; *Goetz*, 45 Fed.Cl. 340; and *Childs*, 33 Fed.Cl. 556, because the injuries in those cases were "clearly apparent" and, thus, different from the facts of this case. *See* Pet. Mem. of Objections at 5. The Special Master, however, cites these cases for propositions that transcend Petitioners' factual distinction.

The Special Master cites *Brice* for the principle that equitable tolling is not available in Vaccine Act cases. *See Markovich*, at 20. The *Brice* decision extends to all cases under the Vaccine Act, as the holding concerns statutory interpretation rather than an adjudication of a factual dispute. *See Brice*, 240 F.3d at 1372-1374 ("We determine only that equitable tolling is inconsistent with the existing statutory scheme."). Therefore, whether Ashlyn's injury was known to her parents is irrelevant because, as a matter of law, equitable tolling is never available in Vaccine Act cases.

The Special Master also cites *Brice*, for the principle that a court may not interpret a waiver of sovereign immunity in a way that extends the waiver beyond that which Congress intended. *See Markovich*, at 13, 23. Simply because the facts in this case are distinguishable from the facts in *Brice* does not

relieve the court of its obligation to strictly construe the Vaccine Act's waiver of sovereign immunity.

In addition, the Special Master cites *Goetz* and *Childs* for the holding that the 36-month limitations period begins on occurrence of the first symptom or manifestation of an injury, not the first identification of a link between the symptom or manifestation and the injury. *See Markovich*, at 20-21. Although the *Goetz* and *Childs* decisions preceded the United States Court of Appeals for the Federal Circuit's decision in *Brice*, the later case simply reaffirmed the holding in *Goetz* and *Childs*. *See Brice*, 240 F.3d at 1373 ("[T]he statute of limitations here begins to run upon the first symptom or manifestation of the onset of injury, even if the petitioner reasonably would not have known at that time that the vaccine had caused an injury."). As such, the Special Master correctly cited *Goetz and Childs*.

Accordingly, the Special Master did not misconstrue *Brice*, *Goetz*, or *Childs*, notwithstanding the factual distinction that Petitioners proffer.

CONCLUSION

Having determined that the onset of Ashlyn's seizure disorder was July 10, 2000, the Special Master correctly concluded that the United States Court of Federal Claims does ***336** not have jurisdiction to entertain Petitioners' claim. The Vaccine Act states that a Vaccine Injury Table claim, relating to a post-Act vaccine, must be filed within three years of the date of the first symptom or manifestation of onset. *See* 42 U.S.C. § 300aa-

16(a)(2). In this case, Petitioners were required to file a claim for Ashlyn's seizure disorder by July 10, 2003. Petitioners, however, did not file their claim until August 29, 2003-fifty days beyond the limitations period. As such, the Special Master correctly dismissed the Petition.

For the foregoing reasons, Petitioners' Motion for Review is **DENIED**. The Clerk of the Court is hereby directed to enter judgment in accordance with this Memorandum Opinion.

IT IS SO ORDERED.

Fed.Cl.,2005.
Markovich ex rel. Markovich v. Secretary of Dept. of Health and Human Services
69 Fed.Cl. 327

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IN THE UNITED STATE COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
FILED: July 22, 2005

MICHAEL and MELISSA MARKOVICH, as parents of ASHLYN M. MARKOVICH, Petitioners,	*	
v.	*	No. 03-2015V
SECRETARY OF HEALTH AND HUMAN SERVICES Respondent.	*	

Mark L. Krueger, Baraboo, Wisconsin, for Petitioners.

Traci R. Patton, United States Department of Justice, Washington, D.C., for Respondent.

DECISION[1]

SWEENEY, Special Master

On August 29, 2003, Michael Markovich and Melissa Markovich, as the parents of Ashlyn M. Markovich ("Ashlyn"), filed a petition for

[1] The court encourages the parties to review Vaccine Rule 18, which affords each party 14 days to object to disclosure of (1) trade secret or commercial or financial information that is privileged or confidential or (2) medical information that would constitute "a clearly unwarranted invasion of privacy."

compensation under the National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. §§ 300aa-l to -34 (2000 & Supp. II 2003), which alleges that Ashlyn sustained a seizure disorder and intractable epilepsy as the result of her July 10, 2000 diphtheria, tetanus, and acellular pertussis ("DtaP"),[2] inactivated polio virus ("IPV"),[3] and haemophilus influenzae type b ("Hib")[4] vaccinations. The facts of this case present an onset issue; the disposition of which determines whether the special master can exercise jurisdiction over the petition.

According to the petition and Ms. Markovich's affidavit, repeated eye blinking episodes, which began on July 10, 2000, the date Ashlyn received her vaccinations, were the precursor of Ashlyn's seizure disorder. However, Ashlyn's first full-blown seizure

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[2] The DTaP vaccine is "a combination of diphtheria toxoid, tetanus toxoid, and pertussis vaccine; administered intramuscularly for simultaneous immunization against diphtheria, tetanus, and pertussis." Dorland's Illustrated Medical Dictionary 1998 (30th ed. 2003).

[3] The IPV vaccine is "a suspension of formalin-inactivated poliovirus ... administered intramuscularly or subcutaneously for immunization against poliomyelitis." Dorland's Illustrated Medical Dictionary, supra note 2, at 2000.

[4] The haemophilus influenzae type b vaccine protects against infection by the haemophilis influenzae type b bacterium. Dorland's Illustrated Medical Dictionary, supra note 2, at 1999.

did not occur until August 30 or 31, 2000.[5] The parents claim that because they were unaware that the repeated eye blinking episodes were the harbinger of their daughter's seizure disorder, they lacked actual knowledge of a Vaccine Act injury or claim. Thus, the threshold question to be addressed is whether the date of onset is July 10, 2000, the date that the repeated eye blinking episodes began, or August 30, 2000, the date specified in the petition and medical records as the date of Ashlyn's first full-blown seizure. The evidence presented in lay and expert affidavits, expert reports, and expert testimony at hearing leads the special master to conclude that the first symptom or manifestation of onset of Ashlyn's seizure disorder occurred on July 10, 2000, the date that the repeated eye blinking episodes, clear neurological symptoms, began. Unfortunately for petitioners, they filed their petition 50 days after the expiration of the 36-month limitations period prescribed in 42 U.S.C. § 300aa-16(a)(2). As a consequence, the special master is

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[5] The date of onset as reflected in the contemporaneous medical records deviates by one day from the onset date specified in the petition. Petitioners claim Ashlyn's first seizure occurred on August 30, 2000. However, the records from the emergency department at Fairview Ridges Hospital document that the first pronounced seizure occurred on August 31, 2000. Pet. Ex. 14 at 30-33. Similarly, ambulance transfer records also date the first seizure as occurring on August 31, 2000. Pet. Ex. 18 at 5. Because the petition was filed on August 29, 2003, the determination as to whether the first seizure occurred on August 30 or 31, 2000, would not affect the statute of limitations analysis. Accordingly, despite the evidence in the medical records to the contrary, for the sake of simplicity, the special master will use the date specified in the petition, August 30, 2000, as the date of Ashlyn's first seizure.

compelled by statute and the well-settled binding precedent of the United States Court of Appeals for the Federal Circuit ("Federal Circuit") to dismiss the petition for lack of subject matter jurisdiction.

I. PROCEDURAL HISTORY

On August 29, 2003, Michael and Melissa Markovich filed a petition alleging that their daughter Ashlyn's seizure disorder and intractable epilepsy were caused by the DTaP, IPV, and/or HiB vaccines Ashlyn received on July 10, 2000. The petition alleges, inter alia, that after Ashlyn's July 10, 2000 vaccinations and continuing to August 30, 2000, the parents observed Ashlyn rapidly blinking her eyes, realizing now that these episodes may have been seizures.[6] Pet. at ¶ 3. At the time, her parents thought Ashlyn was merely tired; consequently, no medical attention was sought. Id. Ms. Markovich's affidavit supports the averments of the petition. Pet's Aff. at ¶ 4.

Petitioners filed Ashlyn's medical records, Ms. Markovich's affidavit, the expert affidavits of Frank

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[6] All references to the Petition shall be designated herein as "Pet. at ¶ ___." All references to the Affidavit of Melissa Markovich shall be designated herein as "Pet. Aff. at ¶ ___." All references to the pertinent Petitioners' Exhibit shall be designated herein as "Pet. Ex. ___ at ___."

J. Ritter, M.D.,[7] Pet. Ex. 12, and Donald H. Marks, M.D., Ph.D.,[8] Pet. Ex. 17, and an expert report from Jean-Ronel Corbier, M.D.,[9] Pet. Ex. 20.

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[7] On October 27, 2003, petitioners filed the signed affidavit of Frank J. Ritter, M.D., which differed from his unsigned affidavit submitted with the petition. Pet. Ex. 12. The signed affidavit, dated October 7, 2003, purports to establish onset within the statute of limitations, but does not support a causation theory; the affidavit indicates that the cause of Ashlyn's "seizure disorder and/or epilepsy is unknown at this time." Id. at 2.

[8] Dr. Marks's affidavit, dated February 26, 2004, states that "[i]t is more likely than not (probable) that the DTaP vaccination that was given to Ashlyn Markovich on or about July 10, 2000, was causally responsible for the development of the seizure disorder which occurred on or about August 31, 2000." Pet. Ex. 17 at 2.

[9] The expert report of Dr. Corbier, petitioner's testifying pediatric neurologist, recites that a review of Ashlyn's complete medical history reveals that Ashlyn's seizures were the result of multifocal cortical cerebral dysfunction and were caused by the vaccinations received on July 10, 2000. Pet. Ex. 20 at 3-4. Dr. Corbier's report notes that according to Ashlyn's parents, her rapid eye blinking episodes began the same day as her vaccinations and continued through August 30, 2000, the date of her first full-blown seizure. Id. at 1. Dr. Corbier opined that "there may be an underlying, perhaps undiagnosed neurometabolic defect, that, coupled with the two-month set of immunizations, triggered [Ashlyn's] epilepsy." Id. at 3-4. Regardless, Dr. Corbier's report makes clear that the timing of the July 10, 2000 vaccinations was a critical element of his opinion:

> [T]here is a possibility that these rapid frequent eye blinking episodes may have represented seizures. These could have either been brief complex partial seizures or generalized absence seizures. From a timing standpoint, assuming these were in fact seizures, one has to consider

Respondent's Rule 4(b) Report, filed on December 3, 2003, did not recommend compensation. In his report, respondent conceded that there is no mention in the medical records of Ashlyn's eye fluttering, which occurred between the vaccinations administered on July 10, 2000, and Ashlyn's first full-blown seizure on August 30, 2000. Pet. at ¶¶ 3-4, 11. However, respondent did focus on paragraph 3 of the petition, which alleges that, with hindsight, petitioners "now know [that the eye blinking episode] may have been seizures." Resp't Rep. at 2. The Rule 4(b) Report further notes that, "A record dated September 20, 2001, indicates that Ashlyn's mother understood that Ashlyn's eye blinking was seizure activity." Id. at 5; see also Pet. Ex. 7 at 42.

On January 27, 2004, the court held a status conference to discuss further proceedings. During the status conference, the special master stated that an onset hearing with expert testimony was necessary because the petition and Ms. Markovich's affidavit implicated the statute of limitations. Respondent's counsel stated her intention not to offer an expert witness to interpret the significance of the repeated eye blinking episodes, but rather to

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> that one or more of the vaccines given could have potentially served as a trigger factor for the development of epilepsy. Owing to what is known about pertussis and its neurological complications, including seizures, this would be a reasonable consideration. An alternative to this explanation would be that the eye blinking, again assuming that these might represent seizures, occurred coincidentally after the immunizations and were unrelated. In my opinion, this would be a much less likely possibility.

Id. at 3.

rely upon the contents of Ms. Markovich's affidavit. It is beyond the purview of a special master to determine what constitutes a "symptom" and to determine the significance of a symptom. In this case, expert testimony was crucial to determine whether Ashlyn's eye blinking episodes constituted the onset of her seizure disorder. The undersigned was unwilling to speculate on this issue. Therefore, petitioners' counsel agreed to produce an expert to opine on this issue and was given additional time to file an expert report concerning onset.

On June 2, 2004, petitioners' counsel filed the expert report of Dr. Corbier, a pediatric neurologist. Portions of Dr. Corbier's expert report highlighted the statute of limitations issue. Specifically, Dr. Corbier explained that the onset of Ashlyn's seizure disorder occurred on August 30 or 31, 2000, but that some symptoms may have occurred prior to that time. Because there can be only one date for the first symptom or manifestation of onset, the special master conducted an onset hearing on November 5, 2004, in Washington, D.C. Only one witness, Dr. Corbier, testified.

II. FACTUAL HISTORY

Ashlyn was born on May 12, 2000, in Edina, Minnesota, to Melissa and Michael Markovich.[10] Pet. Ex. 1 at 1. According to Ashlyn's pediatrician, Jane O'Neil, M.D., Ashlyn was born fullterm and

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[10] Prenatal records can be found at Petitioners' Exhibits 8 and 9. Delivery records can be found at Petitioners' Exhibit 10. Delivery was achieved by vacuum. Pet. Ex. 10 at 1.

her first two well-baby examinations were normal. Pet. Ex. 3 at 1; see also Pet. Ex. 4 at 6.

On May 26, 2000, Ashlyn had her two-week well-baby examination at Fairview Cedar Ridge Clinic. Pet. Ex. 4 at 6. Mary Homan, M.D., noted that Ms. Markovich was concerned about Ashlyn's feeding, but the pediatrician found that Ashlyn was gaining an appropriate amount of weight. Id. Ashlyn's next visit to her pediatrician was for her two-month well-child visit on July 10, 2000. Pet. Ex. 4 at 3, 6. At this visit, Ashlyn received DTaP, IPV, and HiB vaccinations. Id.; Pet. Ex. 2 at 1-2.

At about 6:00 p.m. on August 31, 2000, one of Ashlyn's parents noted "extremity jerking & staring seizure activity." Pet. Ex. 18 at 5. The parents called the paramedics who arrived and stopped the seizure. Id. Ashlyn was taken to Fairview Ridges Hospital. Pet. Ex. 14 at 30. A head computed tomography scan ("CT scan")[11] was normal. Id. at 34. Ashlyn was discharged from Fairview Ridges Hospital with a diagnosis of seizure of unknown etiology and transferred to St. Paul Children's Hospital ("Children's Hospital"). Id. at 32; Pet. Ex. 3 at 1; Pet.

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[11] A CT scan is a "recording of internal body images at a predetermined plane by means of the tomograph." Dorland's Illustrated Medical Dictionary, supra note 2, at 1919. A tomograph is "an apparatus for moving an x-ray source in one direction as the film is moved in the opposite direction, thus showing in detail a predetermined plane of tissue while blurring or eliminating detail in other planes." Id. In a CT scan, "the emergent x-ray beam is measured by a scintillation counter; the electronic impulses are recorded on a magnetic disk and then are processed by a mini-computer for reconstruction display of the body in cross-section on a cathode ray tube." Id.

Ex. 4 at 5; Pet. Ex. 18 at 5. The cause of the seizure was not identified. Pet. Ex. 4 at 5.

Ashlyn had another well-child examination on September 8, 2000. Pet. Ex. 4 at 5. After noting Ms. Markovich's report of the seizure activity, Tiffani Mullins, M.D., indicated that the examination was normal. Id. That finding notwithstanding, on or about September 14, 2000, Ashlyn had another seizure. Pet. Ex. 6 at 210. Ashlyn experienced additional seizures on October 11, 14, 18, 20, 21, and 22, 2000. Id. On October 16, 2000, Ashlyn was examined by Ronald H. Spiegel, M.D., of Children's Hospital regarding her seizures. Pet. Ex. 16 at 45-46. Ashlyn was started on Tegretol, an antiseizure medication, on October 21, 2000. Pet. Ex. 6 at 210. Ashlyn was also given three chiropractic treatments; but these were discontinued as her seizure activity increased in frequency. Id.

When Ashlyn was admitted to Children's Hospital on October 22, 2000, the Tegretol was discontinued, and a video electroencephalogram ("EEG")[12] was performed. Pet. Ex. 6 at 159-63; 210. According to Dr. Ritter, the EEG "clearly demonstrate[d] seizure onset from the right posterior quadrant." Id. at 159. Ashlyn also underwent a

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[12] An EEG is "a recording of the potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain.... Fluctuations in potential are seen in the form of waves, which correlate well with different neurologic conditions and so are used as diagnostic criteria." Dorland's Illustrated Medical Dictionary, supra note 2, at 596.

magnetic resonance image ("MRI")[13] of her head. Id. at 164. The MRI report indicated "intracranial contents normal" and "small amount of fluid or mucosal thickening in the left mastoid air cells noted." Id.

On November 9, 2000, Dr. Spiegel saw Ashlyn for another follow-up of her epilepsy. Pet. Ex. 16 at 44. Then, on November 17, 2000, Ashlyn had a generalized seizure and was taken by ambulance to Fairview Ridges Hospital. Pet. Ex. 14 at 23-26; Pet. Ex. 18 at 12. Ashlyn was then transferred to Children's Hospital in status epilepticus.[14] Pet. Ex. 14 at 26; Pet. Ex. 16 at 4-5; Pet. Ex. 18 at 12. At Children's Hospital, Ashlyn underwent a video EEG, which was normal for a child her age. Pet. Ex. 6 at 155-58. Ashlyn was discharged on November 20, 2000. Pet. Ex. 16 at 4.

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[13] An MRI is "a method of visualizing soft tissues of the body by applying an external magnetic field that makes it possible to distinguish between hydrogen atoms in different environments." Dorland's Illustrated Medical Dictionary, supra note 2, at 908.

[14] Status epilepticus is "a continuous series of generalized tonic-clonic seizures without return to consciousness." Dorland's Illustrated Medical Dictionary, supra note 2, at 1756. A generalized tonic-clonic seizure is "the seizure of grand mal epilepsy, consisting of a loss of consciousness and generalized tonic convulsions followed by clonic convulsions." Id. at 1676. Tonic convulsions are involuntary and are characterized by a "prolonged contraction of the muscles." Id. at 415-16. Clonic convulsions are also involuntary and are characterized by "alternating contraction and relaxation of the muscles." Id. at 415.

Ashlyn was not hospitalized again until January 8, 2001, when she was taken by ambulance to Fairview Ridges Hospital with a seizure. Pet. Ex. 14 at 17-19. A chest x-ray was negative. Id. at 20.

Ashlyn visited her pediatrician's office on January 25, 2001, with a two-to-three week history of cough, congestion, and low grade fevers. Pet. Ex. 4 at 9, 11. A physician's assistant noted that Ashlyn had a seizure with a high fever a couple of weeks prior and had been taken to the emergency room. Id. Ashlyn was diagnosed with a prolonged upper respiratory infection and probable acute bronchitis. Id. Then, later that same day, Ashlyn was taken to Fairview Ridges Hospital with a seizure. Pet. Ex. 14 at 14-16. Several days later, on January 29, 2001, Dr. Spiegel saw Ashlyn for a follow-up visit. Pet. Ex. 16 at 41-42. Dr. Spiegel reported that despite her seizures, Ashlyn was developing well. Id. at 41.

On March 3, 2001, Ashlyn was admitted to the Pediatric Intensive Care Unit ("PICU") at Children's Hospital "following multiple medications to stop seizure." Pet. Ex. 6 at 210. She was discharged within 24 hours. Id.

Ashlyn remained seizure free until March 29, 2001, when she was taken by ambulance to Fairview Ridges Hospital with a generalized tonic-clonic seizure. Pet. Ex. 14 at 4-7; Pet. Ex. 18 at 19. Ashlyn was transferred to Children's Hospital. Pet. Ex. 14 at 5; Pet. Ex. 18 at 19. Several days later, on April 2, 2001, Ashlyn had another seizure and returned to the emergency room. Pet. Ex. 6 at 210. Ashlyn again returned to the emergency room on April 3, 2001,

with yet another seizure. Id.; Pet. Ex. 19 at 2. On that date, Ashlyn was admitted to the PICU for observation and then discharged the following day. Pet. Ex. 6 at 210. But, on April 17, 2001, Ashlyn was again taken to the emergency room because of seizure. Id.

On May 18, 2001, Ashlyn visited Metropolitan Pediatric Specialists, P.A. for her twelve-month well-child visit. Pet. Ex. 5 at 19. Timothy Johanson, M.D., noted that Ashlyn had seizures since age three-and-one-half months and been hospitalized three times for status epilepticus. Id.

On June 8, 2001, Ashlyn was taken to St. Francis Regional Medical Center ("St. Francis") due to a seizure. Id. at 99-100. Ashlyn was transferred to Minneapolis Children's Hospital. Id. at 100-02. Then, on July 10, 2001, Ashlyn again was taken to St. Francis with a seizure. Id. at 89. Manuel Roman, M.D., gave Ashlyn antiseizure medication, which stopped the seizure after ten minutes. Id. at 90. Blood tests were normal except for a mildly elevated white blood cell count. Id. at 90-91. Ashlyn was discharged against medical advice. Id. at 91.

On July 12, 2001, Ashlyn saw Steven Janousek, M.D., at Noran Neurological Clinic on referral for a neurologic assessment. Pet. Ex. 7 at 71-72. Five days later, on July 17, 2001, Ashlyn returned to St. Francis with a seizure. Pet. Ex. 5 at 92-93. Between July 18, 2001, and April 26, 2002, Ashlyn's mother frequently telephoned the Noran Neurological Clinic to update Dr. Janousek on Ashlyn's progress, discuss adjustment of Ashlyn's

medications, inquire about seizure management, or discuss administrative matters. See generally Pet. Ex. 7.

On July 23, 2001, Ashlyn had her urine analyzed for organic acids,[15] amino acids,[16] and oligosaccharides.[17] Pet. Ex. 5 at 34-36. The interpreting physician found, "This specimen was screened for all organic acids which are diagnostic of organic acidurias. The organic acid pattern seen is not consistent with that of a known aciduria."[18] Id. at 34. In addition, the physician wrote, "This urine amino acid pattern is not consistent with a known disorder of amino acid metabolism." Id. Finally, the physician indicated that the oligosaccharides screen was normal. Id. at 35.

On July 31, 2001, Ashlyn again returned to St. Francis with a seizure. Id. at 97. James S. Parker, M.D., noted that Ashlyn had been seizing for

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[15] An organic acid is an acid that contains one or more carbon atoms. Dorland's Illustrated Medical Dictionary, supra note 2, at 16.

[16] An amino acid is "any organic compound containing an amino and a carboxyl group." Dorland's Illustrated Medical Dictionary, supra note 2, at 16.

[17] An oligosaccharide is "a carbohydrate that on hydrolysis yields a small number of monosaccharides." Dorland's Illustrated Medical Dictionary, supra note 2, at 1306. A monosaccharide is a "simple sugar; a carbohydrate that cannot be decomposed by hydrolosis." Id. at 1172.

[18] Aciduria is the "excess of acid in the urine." Dorland's Illustrated Medical Dictionary, supra note 2, at 17.

approximately ten minutes at the time of arrival and administered antiseizure medication, which finally resolved the seizure. Id. at 97-98. Ashlyn was admitted to the hospital for further observation as she recovered from sedation and the antiepileptics. Id. at 98.

On August 7, 2001, Ashlyn had another brain MRI, which was normal. Pet. Ex. 7 at 27. Despite her normal MRI, Ashlyn returned to St. Francis on August 11, 2001, and August 24, 2001, with seizures. Pet. Ex. 5 at 31-32, 85-88; Pet. Ex. 18 at 31. On August 24, 2001, Ashlyn was transported by air to Minneapolis Children's Hospital. Pet. Ex. 5 at 87-88; Pet. Ex. 7 at 25-26; Pet. Ex. 18 at 31. A repeat MRI was normal and Ashlyn was placed on antiseizure medication. Pet. Ex. 7 at 26. Ashlyn was discharged on August 25, 2001. Id. at 25-26.

On August 28, 2001, Ashlyn saw Dr. Janousek for a follow-up visit. Id. at 58. Subsequently, Ashlyn was admitted to the pediatric epilepsy ward at Children's Hospital on September 10, 2001, with the goal of starting the ketogenic diet.[19] Pet. Ex. 6 at

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[19] According to The Epilepsy and Brain Mapping Program:

> The ketogenic diet is a stringent, mathematically calculated diet high in fat and low in protein and carbohydrates that, when followed conscientiously, produces a by-product called ketones in patients' blood and urine. High concentrations of ketones in the body control the frequency and severity of seizures, although the biochemical mechanisms for this phenomenon are not yet known.

202-06, 209-13, 216. She underwent a video EEG throughout her admission. Id. at 150-54. Ashlyn also was evaluated by the Speech Pathology Department to assess her communication skills. Id. at 89. The speech pathologist found that Ashlyn had a mild receptive and expressive language delay. Id. Ashlyn was discharged on September 13, 2001. Id. at 202-05.

On September 17, 2001, October 5, 2001, and October 15, 2001, Ashlyn returned to St. Francis with further seizures. Pet. Ex. 5 at 79-84.

Between November 4, 2001, and June 27, 2003, Ashlyn's mother frequently telephoned the Minnesota Epilepsy Group, P.A., to update Dr. Ritter on Ashlyn's progress, discuss adjustment of Ashlyn's medications, inquire about seizure management, or discuss administrative matters. See generally Pet. Ex. 6.

On November 8, 2001, Ashlyn was taken to St. Francis with a seizure unresponsive to rectal Valium.[20] Pet. Ex. 18 at 24. Ashlyn had a chest x-ray that was normal. Pet. Ex. 5 at 28. Ashlyn was

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The Epilepsy and Brain Mapping Program, The Ketogenic Diet, at http://www.epipro.com/k_diet.html (last visited July 21, 2005).

[20] Valium is the trademark for the drug preparation of diazepam. Dorland's Illustrated Medical Dictionary, supra note 2, at 2003. Diazepam is a benzodiazepine used as, among other things, an anticonvulsant and as an antitremor agent. Id. at 512.

transferred to the PICU at Minneapolis Children's Hospital. Pet. Ex. 6 at 214-15; Pet. Ex. 18 at 24.

On November 13, 2001, Ashlyn saw Dr. Ritter for a follow-up to her hospital admission and for a second opinion. Pet. Ex. 6 at 116-19. Dr. Ritter reported that "Ashlyn continues to have ongoing seizures with frequent episodes of status epilepticus. Seizures typically do not stop with the administration of rectal Valium and therefore require[] emergency medical intervention." Id. at 119. Dr. Ritter planned to ascertain what testing regarding the etiology of the seizures had been done and adjusted Ashlyn's antiseizure medication. Id.

On December 7, 2001, Ashlyn was taken to St. Francis several times. Pet. Ex. 5 at 75-76. John Baker, M.D., stated that in the afternoon, Ashlyn's mother noted cluster seizure activity and brought Ashlyn to the hospital because Ashlyn became lethargic after the administration of Valium. Id. at 75. Ashlyn returned to the hospital later that afternoon with questionable seizure activity. Id. Within an hour of her discharge, Ashlyn returned again with a recurrence of seizure activity and was admitted for observation. Id.

On December 26, 2001, Ashlyn was admitted to Children's Hospital for "clarification of seizures, medication adjustment, PT, OT and speech evaluation to determine baseline developmental status and [etio]logic evaluation to determine cause for seizures if not done previously." Pet. Ex. 6 at 193-96. Michael D. Frost, M.D., noted that although Ashlyn had been treated with multiple

anticonvulsant medications and the ketogenic diet, she still had daily seizures. Id.

During her hospitalization, Ashlyn "underwent prolonged evaluation with difficult to control seizures." Id. Her physicians performed a video EEG which "revealed generalized spike and polyspike and wave or frontally dominant epileptiform discharges." Id. at 141-49, 196. Before she was discharged, Ashlyn's physicians made additional changes to her medication regimen.[21] Id. at 194-96.

Also during this admission, Ashlyn was evaluated by the Speech Pathology Department to reassess her communication skills. Id. at 87-88. Once again, the speech pathologist found that the gap between Ashlyn and her peers was growing slightly in communication skills. Id. at 87. Ashlyn also was evaluated by the Physical Therapy Department and the Occupational Therapy Department. Id. at 172-76. Ashlyn was discharged from Children's Hospital on January 11, 2002, with diagnoses of intractable epilepsy, partial tonic seizures and complex-partial secondary generalized seizures, a history of status epilepticus, and a history of Todd's paralysis.[22] Id. at 196.

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[21] A listing of the antiepileptic medications tried by Ashlyn can be found at Petitioners' Exhibit 6 at 256-57.

[22] Todd's paralysis, also known as postepileptic paralysis, is "hemiparesis or monoparesis lasting for a few minutes or hours, or occasionally for several days, after an epileptic seizure." Dorland's Illustrated Medical Dictionary, supra note 2, at 1366.

On January 11, 2002, after being discharged from Children's Hospital, Ashlyn was taken to St. Francis with a seizure. Pet. Ex. 5 at 68. Brian Clarkowski, M.D., administered antiseizure medication which resolved her seizure. Id. at 69.

Ashlyn visited Metropolitan Pediatric Specialists, P.A. on January 17, 2002, for her eighteen month well-child visit and blood work. Id. at 15. Judith Snook, M.D., noted "normal growth, developmental] delay, [and] intractable seizures." Id.

On January 24, 2002, Ashlyn underwent a two-hour video EEG. Pet. Ex. 6 at 139-40. According to Dr. Ritter, "This EEG would suggest diffuse cortical dysfunction with multiple areas of potential epileptogenesis, as well as areas of more generalized and diffuse, but somewhat irregular spike-wave or polyspike wave." Id. at 140.

Five days later, on January 29, 2002,[23] Ashlyn was admitted to the Mayo Clinic by Jeffrey R. Buchhalter, M.D., to determine whether "a single focus of seizure onset is likely that would be susceptible to surgical removal." Pet. Ex. 15 at 8. Dr. Buchhalter discussed with Ms. Markovich the possiblity of an immunologically-mediated seizure disorder. Id. at 16. Upon admission, neurologist Randa G. Jarrar, M.B.B.S.,[24] reported that Ashlyn experienced four types of seizures: (1) repeated eye

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[23] Ashlyn had been referred to the Mayo Clinic by Dr. O'Neil on February 2, 2001. Pet. Ex. 4 at 10.

[24] An M.B.B.S. is the abbreviation for a bachelor of medicine and bachelor of surgery.

blinking; (2) elonic movement of the face, arm, and leg; (3) generalized seizures with or without focal onset; and (4) partial motor seizures. Id. at 12. Dr. Jarrar also noted that Ashlyn was developing appropriately for her age with the exception of her speech. Id. at. 13. Dr. Jarrar diagnosed intractable epilepsy and discussed with Ms. Markovich the remaining treatment options, including other medications and surgery. Id. at 14. Ashlyn was admitted to the Epilepsy Monitoring Unit and had a computer-assisted prolonged video EEG from January 30, 2002, to February 3, 2002. Id. at 2-3,14. The EEG revealed evidence of multifocal epileptic abnormalities. Id. at 2-3. Dr. Buchhalter noted that because Ashlyn's seizures had different foci, surgical intervention was not indicated. Id. at 20. Ashlyn was discharged on February 19, 2002. Id. at 19.

On February 17, 2002, February 22, 2002, twice on March 17, 2002, and April 5, 2002, Ashlyn returned to St. Francis with seizures. Pet. Ex. 5 at 52-55, 64-67. At the surgical conference held at Minnesota Epilepsy Group on April 9, 2002, Ashlyn was recommended for the implantation of a vagus nerve stimulator ("VNS").[25] Pet. Ex. 6 at 242.

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[25] According to The Epilepsy and Brain Mapping Program:

> The vagus nerve is one of the primary communication lines from the major organs of the body to the neck to the vagus nerve. Stimulation of the vagus nerve can stop seizures, reduce the intensity and frequency of seizures in some patients. The VNS periodically stimulates the vagus nerve, usually for a brief period.
>
> The VNS is an implanted pacemaker-size stimulator. It has a wire lead that attaches to the vagus nerve by means

Ashlyn was admitted to Children's Hospital on April 16, 2002, "for video EEG to clarify events and then determine treatment options." Id. at 185-87. Multiple events were recorded on the EEG. Id. at 128. The EEG "strongly suggested a frontal onset to seizures." Id. Ashlyn was discharged on April 18, 2002.[26] Id. at 186.

On April 29, 2002, Ashlyn was taken to St. Francis with a seizure. Pet. Ex. 5 at 48=49. Dr. Clarkowski noted that Ashlyn "had a focal seizure of just focal eye twitching and nystagmus for approximately 30 minutes." Id. The antiseizure medication resolved the seizure. Id. at 49.

Ashlyn's mother telephoned the Minnesota Epilepsy Group on April 30, 2002, because of a one-and-a-half hour long seizure Ashlyn had the previous night. Pet Ex. 6 at 5. Ashlyn's mother reported a dramatic reduction in eye flutters, but felt that Ashlyn was out of control the previous night and wanted to speak with Dr. Ritter. Id.

> of an incision. The incision is made on a naturally occurring crease on the neck, thereby making the healed scar practically invisible. The procedure takes a few hours and the patient is usually released from the hospital on the next day. After the patient stabilizes, the physician uses a wand to activate the VNS.

The Epilepsy and Brain Mapping Program, Vagus Nerve Stimulator, at http://www.epipro.com/vns.html (last visited July 21, 2005).

[26] A listing of the antiepileptic medications administered to Ashlyn between January 11, 2002, and April 17, 2002, can be found at Petitioners' Exhibit 6 at 258-60.

After being free of seizures for three weeks, Ashlyn was taken to St. Francis on June 23, 2002, with a seizure. Id. at 46-47. Dr. Roman gave Ashlyn medication which resolved the seizure. Id. However, Ashlyn returned later that day after vomiting and resuming atypical seizure activity. Id. at 50-51. Antiseizure medication again resolved Ashlyn's seizure. Id. at 51. Ashlyn was again seen at St. Francis for another seizure on August 11, 2002. Id. at 29-30. On August 27, 2002, Ashlyn saw Dr. Ritter for a follow-up visit. Pet. Ex. 6 at 352-55.

On October 8, 2002, Ashlyn had a physical examination in preparation for the implantation of her VNS. Id. at 181-84. Then, on October 10, 2002, Ashlyn had the VNS implanted by Mary E. Dunn, M.D., at Children's Hospital. Id. at 96, 178-80. Unfortunately, the VNS flow sheets dated from October 15, 2002, to April 10, 2003, indicate that minimal to no improvement occurred with Ashlyn's seizures.[27] Id. at 165-71. Ashlyn was discharged on October 11, 2002. Id. at 180.

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[27] On January 27, 2003, Ashlyn saw Dr. Ritter for a follow-up of her intractable epilepsy and for additional adjustment of her VNS. Pet. Ex. 6 at 307-10. In his assessment, Dr. Ritter reported:

> At this time, although Ashlyn has had the vagal nerve stimulator only for approximately a three-month period of time, seizure frequency, intensity, and quality of life remain unchanged.... Family has considerable concerns regarding frequency of seizures despite all the medication changes and placement of the vagal nerve stimulator. Mother also has questions that during her pregnancy at approximately 34 to 35 weeks gestation, fetal bradychardia was noted on two to three occasions; was this related to seizure activity.

On January 3, 2003, Ashlyn underwent a speech and language evaluation at St. Francis Rehabilitative Services by Michelle Laurent, CCC-SLP. Pet. Ex. 5 at 43-45. Ashlyn's mother's primary concerns at this evaluation included Ashlyn's language production and cognitive skills. Id. at 43. Ms. Laurent found that Ashlyn demonstrated significant speech and language delays and recommended that Ashlyn receive therapy to encourage development of her speech and language skills. Id. at 44.

On February 2, 2003, Ashlyn was taken to St. Francis with seizure activity. Id. at 41-42. Dr. Roman tried several medications and eventually was successful in arresting the seizure. Id.

Ashlyn was admitted to Children's Hospital on March 19, 2003. Pet. Ex. 6 at 190-92. The purpose of the admission was to determine other treatment options and to obtain a baseline recording to determine whether Ashlyn's seizures had changed. Id. at 190. During her admission, Ashlyn was started on various antiseizure medications. Id. at 191. In addition, the surgical option of an anterior two-thirds corpus callosotomy[28] was discussed. Id. Ashlyn was discharged on March 22, 2003. Id. at 190-92.

Id. at 310.

[28] A corpus callosotomy is the "surgical transection of the fibers in the corpus callosum ...; formerly used to treat intractable epilepsy." Dorland's Illustrated Medical Dictionary, supra note 2, at 423.

On April 25, 2003, and June 19, 2003, Ashlyn was taken to St. Francis with a seizure. Pet. Ex. 5 at 37-40. As a result of his treatment of Ashlyn during her previous visits to the emergency department for seizure activity, Dr. Clarkowski tried several antiseizure medications until Ashlyn's seizure was resolved. Id. at 37-38, 40.

On July 28, 2003, an MRI of Ashlyn's brain revealed:

1. Small ill-defined focus of signal abnormality is seen in the deep right mid frontal white matter. This is nonspecific, but is compatible with nondescript gliosis.
2. Possible mild-to-moderate atrophy of the right hippocampal complex.
3. Intracranial contents otherwise unremarkable.
4. Inflammatory changed noted bilaterally in the ethmoid and maxillary paranasal sinuses.

Pet. Ex. 11 at 4.

III. DISCUSSION

A. The Vaccine Act and Waiver of Sovereign Immunity.

"The United States, as sovereign, is immune from suit save as it consents to be sued." United States v. Sherwood, 312 U.S. 584, 586 (1941). Specifically, "a statute of limitations is a condition

on the waiver of sovereign immunity by the United States, and courts should be careful not to interpret [a waiver] in a manner that would extend the waiver beyond that which Congress intended." Brice v. Sec'y of HHS, 240 F.3d 1367, 1370 (Fed. Cir. 2001) (citations and internal quotations omitted). "The court cannot expand on the waiver of sovereign immunity explicitly stated in the statute." McGowan v. Sec'v of HHS, 31 Fed. Cl. 734, 740 (1994) (citing Broughton Lumber Co. v. Yeutter, 939 F.2d 1547, 1550 (Fed. Cir. 1991)). Moreover, the statute of limitations may not be waived by either the court or the parties. Forman v. United States, 329 F.3d 837, 841-42 (Fed. Cir. 2003).

The Vaccine Act is a waiver of the sovereign immunity of the United States because it permits people with vaccine-related injuries, as well as the legal representatives of people who have suffered a vaccine-related death, to sue the United States for compensation. The right to sue is not unconditional- the Vaccine Act contains a statute of limitations that places a condition on the waiver of sovereign immunity. The express limitations provision of the Vaccine Act provides that for vaccines listed in the Vaccine Injury Table ("Table"):[29]

> if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the

[29] 42 C.F.R. § 100.3(a). The DTaP, IPV, and Hib vaccinations are included on the Table.

> occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury

42 U.S.C. § 300aa-16(a)(2) (emphasis added). In other words, the United States waives its sovereign immunity only for 36 months in instances of vaccine-related injury. After 36 months, the United States is immune from suit.

The court is obligated to dismiss a petition as soon as it finds that it lacks jurisdiction to decide the merits of a case. See Steel Co. v. Citizens for a Better Env't. 523 U.S. 83, 94 (1998) ("Without jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause."), citing Ex parte McCardle, 74 U.S. (7 Wall.) 506, 514(1868).

B. Threshold Jurisdictional Issue.

The threshold question presented in this case is whether the August 29, 2003 petition was filed within the three-year limitations provision specified by the Vaccine Act. To satisfy the limitations provision of the Vaccine Act, Ashlyn's symptoms must have begun on or after August 29, 2000; otherwise the petition is untimely. The petition, coupled with Ashlyn's mother's affidavit and petitioners' expert reports, implicates the statute of limitations. Specifically, the petition avers:

> At times after the immunization of July 10, 2000, until August 30, 2000, Michael and Melissa Marckovich observed Ashlyn having episodes in which Ashlyn would rapidly blink her eyes. Petitioners now know that these episodes may have been seizures although at the time they thought she was tired. The first episode was approximately July 10, 2000. No medical attention was sought during this time due to there being no apparent cause for concern.

Pet. at ¶ 3. Further, Ms. Markovich's affidavit explained that on July 10, 2000, after Ashlyn had received her vaccinations at the Fairview Cedar Ridge Clinic, she "thought... Ashlyn was just sleepy, [but] I am now aware she may have been having seizures between the time of the immunization and August 30, 2000, when she had her first serious episode." Pet. Aff. at ¶ 4. Therefore, the critical jurisdictional issue to be resolved is whether the repeated eye blinking episodes, which began on July 10, 2000, were, in fact, the first symptom or manifestation of onset of Ashlyn's seizure disorder, thus triggering the statute of limitations.

The parties provided differing views as to the date of onset. Petitioners contend, relying on the contemporaneous medical records, that the first symptom or manifestation of onset occurred on August 30, 2000, the date Ashlyn was rushed to the hospital with her first seizure. To support their assertion, petitioners argue that although the first eye blinking episode, which occurred on July 10, 2000, may have been the harbinger of Ashlyn's

seizure disorder, as laypersons, they lacked the requisite medical education and training to comprehend the significance of the first episode. The parents observed the repeated rapid eye blinking episodes, but assumed that, on those occasions, Ashlyn was fluttering her eyes because she was sleepy. Sadly, they were unaware that what they had begun to witness was the first neurological symptom that either signaled their daughter's brain disorder or was a subtle seizure. According to the petition and Ms. Markovich's affidavit, it was not until after the August 30, 2000 seizure that the petitioners became aware of the significance of the earlier eye blinking events. Thus, the parents argue, it was impossible for them to make the necessary linkage between rapid eye blinking and injury. For this reason, petitioners urge the special master to find August 30, 2000, as the date of onset. In essence, petitioners argue that their inability to recognize the significance of the first symptom of their child's debilitating disorder delays the running of the limitations period.

Conversely, respondent contends that because Ashlyn's July 10, 2000 rapid eye blinking was the first symptom of Ashlyn's seizure disorder, the plain language of the statute requires that the 36-month period began running on that date. According to the respondent, the limitations period is triggered by the first symptom or manifestation of onset, not by petitioners' actual knowledge or awareness of a claim arising under the Vaccine Act. Indeed, respondent argues that petitioners need not know that their child suffered a vaccine-related injury. Rather, respondent contends, it is sufficient that

these parents were aware of the July 10, 2000 eye blinking episode-the Markovichs need not have been aware of the significance.

Because the resolution of this factual issue is critical to the court's exercise of subject-matter jurisdiction, the court conducted an onset hearing. As explained below, because petitioners' expert witness conceded that the rapid eye blinking episode witnessed by Ashlyn's parents on July 10, 2000, was the first symptom or manifestation of onset of Ashlyn's seizure disorder, the special master is required to dismiss the petition as beyond the limitations period.

1. Dr. Corbier's Testimony Makes Plain that the July 10, 2000 Rapid Eye Blinking Episodes Constituted the Onset of Ashlyn's Seizure Disorder.

Petitioners offered only one witness at hearing, Dr. Corbier. Dr. Corbier was awarded his medical degree in 1995 and became board-certified in pediatric neurology in 2000.[30] Tr. at 5-6. Dr. Corbier treats both adults and children with seizures. Id. at 6. Dr. Corbier explained that a seizure disorder and epilepsy are the same thing; however, with seizure disorders, an individual can experience multiple seizures daily. Id. at 7.

Dr. Corbier also opined that DPT vaccinations can cause seizure disorders in susceptible individuals. Id. Based upon his review of Ashlyn's

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[30] All references to the Transcript of the November 5, 2004 proceedings shall be designated herein as "Tr. at___."

medical records and her clinical picture, Dr. Corbier confirmed the opinion of his May 19, 2004 report that on August 30, 2000, Ashlyn had a generalized tonic-clonic seizure that lasted at least 20 minutes. Id. at 9. With regard to the rapid eye blinking episodes, which were the focus of the onset hearings Dr. Corbier testified:

> Well, they play an important part, in the sense that from my understanding of the records it seems that on July 10th, 2000, the very day of her vaccinations, there was some blinking of the eye. What is unclear is whether it could have been the beginning of some small unrecognized seizure activity.
>
> That could sometimes be subtle, or it could be some type of beginning of a brain dysfunction that would have culminated to a full-fledged, first full seizure on August 30th.
>
> So my professional opinion is that the time line of when something first [] may have started on August 10th. [sic][31] that was due to some type of cerebral dysfunction, and then the results culminated in her having a seizure, a generalized tonic, or grand mal seizure as we call it, on August 30th.

Id. at 10 (emphasis and footnote added). Dr. Corbier explained that although rapid eye blinking alone is

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[31] Dr. Corbier misstated the date of the eye blinking episode and almost immediately corrected the record to reflect the correct date, July 10, 2000. Tr. at 10.

insufficient to establish a seizure disorder diagnosis, as a neurologist, the eye blinking episode would have raised his suspicions and he would have pursued further investigation:

> If we had a situation where someone started having eye blinking for no apparent reason, then we start to ask questions. There are certain things beyond the eye blinking that would raise our level of suspicion more and more in terms of seizure activity, such as observation of a loss of consciousness, ideation, and what we call post-spectral changes.
>
> For instance, if someone has a lot of eye blinking, and then subsequently become[s] very tired or confused, that would be some of the traditional clinical findings that would raise my level of suspicion.
>
> So eye blinking by itself would not lead necessarily to seizures, but would at least lead to a suspicion and the need for further questioning and evaluation.

Id. at 11 (emphasis added). Dr. Corbier further testified that he could not state with certainty whether the eye blinking episodes themselves constituted seizure activity, explaining:

> It is hard for me to say definitively that it was or was not a seizure,... the only way to be certain would be to have an EEG done at

> that time while the eye blinking was going on and correlating it with EEG changes.
>
> Short of that, what we can do is suspect that there are one or two possibilities. One is that the eye blinking could have either been some small seizures, subtle seizures if you will, or there is also the possibility that it could have been some type of brain dysfunction that started at that time, and manifesting as involuntary eye blinking.
>
> And with progressive dysfunction, that person then on August 30th had a full-fledged seizure, and went on to have ... more and more seizures, and you can see that there was a progression of symptoms.

Id. at 12 (emphasis added). This testimony is significant for two reasons. First, either possibility posited by Dr. Corbier, a subtle seizure or a brain dysfunction, reflects that the child had a malady that was manifested by a clear neurological symptom-eye blinking.[32] Therefore, regardless of the ultimate conclusion-subtle seizure or brain

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[32] Later in his testimony, Dr. Corbier again confirmed his prior testimony that Ashlyn's July 10, 2000 rapid eye blinking reflected cerebral dysfunction. Id. at 15-16. Specifically, Dr. Corbier testified that he thought it likely that a brain dysfunction caused the July 10, 2000 eye blinking episode, that the brain dysfunction led to the development of the seizure disorder, and that the first full-blown seizure occurred on August 30, 2000. Id. at 18-19. Finally, Dr. Corbier testified that the eye blinking and development of seizure disorder were all part of the same process. Id. at 19. The special master find this evidence compelling.

dysfunction-it was clear and unmistakable that Ashlyn's rapid eye blinking was not normal. It is not relevant to the onset query that the parents were unaware that the blinking episodes were a neurological symptom that served as the precursor to the seizure that Ashlyn would experience on August 30, 2000. What is relevant to the present discussion is that the parents were aware that the blinking episodes began on July 10, 2000, and continued until the August 30, 2000 seizure.

Second, Dr. Corbier makes plain that the eye blinking episodes were part of a progression of symptoms, which culminated in the August 30, 2000 seizure. This point is further illustrated by the following portion of Dr. Corbier's testimony:

> The part that is very suspicious to me is, number one, the first full-fledged seizure on August 30th was preceded by the eye blinking that according to the record started on July 10th.
>
> In terms of timing, it appears like there was some type of precipitating event in this case with the vaccine and on that same day you have the eye blinking episodes, []regardless of whether the eye blinking turned out to be some type of cerebral dysfunction or little seizure.
>
> And that they progressed on August 30th to a full-blown seizure, and then according to the record the patient continues having a lot of seizures, and what we would term refractory seizures.

> So there have been a lot of evaluations to try to look for alternative diagnoses or causes, and I could not detect any alternative explanations. So looking at that time line, to me, I would say that it was a vaccine related injury causing seizures that could be documented here.

Id. at 14-15 (emphasis added). In arriving at his theory of causation, Dr. Corbier ruled out other causes for Ashlyn's injury. In so doing, Dr. Corbier concluded that the eye blinking episodes, which started on July 10, 2000, marked the onset of first symptom of injury. Therefore, according to Dr. Corbier, Ashlyn's injury was directly tied to the vaccinations, particularly the DTaP vaccine, administered that same day. Specifically, when pressed for an answer as to when the first symptom of the seizure disorder occurred, Dr. Corbier conceded that the first symptom occurred with the July 10, 2000 eye blinking episode: "Yes, I think there was some type of dysfunction of some sort that likely started on July 10th, leading to a documented seizure on August 30th." Id. at 19.

Dr. Corbier acknowledged that the eye blinking episode was, in fact, medically recognized as a neurological symptom of a mild seizure or subtle brain dysfunction. Id. at 22, 24. A symptom that is "subtle" is, nevertheless, manifestation and cannot be ignored. Consequently, the subtlety of the dysfunction notwithstanding, Ashlyn's July 10, 2000 eye blinking episode evidenced the first symptom or manifestation of onset of her seizure disorder.

Throughout his testimony, Dr. Corbier stated that Ashlyn's eye blinking would have made him suspicious and prompted him to ask further questions and conduct an evaluation and order testing. Id. at 11-12,

14,16, 22, 24. This conclusion is reinforced by the following testimony elicited during cross-examination:

> Q But as far as the eye blinking alone,... is [it] not your opinion that that alone is evidence of a seizure disorder?
>
> A There is no question that there was a mild seizure, but in terms of a seizure disorder, and seeing signs or symptoms of a seizure disorder, we would want to see signs or symptoms to strengthen that suspicion.
>
> So the choices really are that it could be mild seizures, or that instead of seizures that there could be some subtle cerebral dysfunction that was starting, and will culminate in a more organized seizure activity down the road. So it is hard to sort those two out.
>
> ...
>
> Q Dr. Corbier, just to clarify for me, would it be your opinion that the eye fluttering and seizure disorder are both symptoms of a single process caused by an insult to the brain at about the time of the vaccinations?

> A Yes, I think that is a likely-that is a good possibility.

Id. at 24-25 (emphasis added). This testimony highlights that Ashlyn's eye blinking was a neurological symptom that marked onset. Dr. Corbier made clear that even though he could not have said with absolute certainty on July 10, 2000, that Ashlyn had a seizure disorder, he was able to testify that problematic neurological symptoms were present. This adverse testimony by petitioners' expert, a highly qualified neurologist and a credible witness, was critical to the special master's decision. It proved that from an objective standpoint, onset was manifest even though the parents did not recognize its significance. It is readily apparent from his testimony that Dr. Corbier found that Ashlyn's eye blinking was a sign of neurological injury. It is irrelevant that a neurologist would not have been able to make an immediate diagnosis of the specific injury on July 10, 2000. It is enough that the eye blinking episodes represented the beginning of a seizure disorder.

It is also worth noting that Dr. Corbier stressed the importance of the eye blinking episodes occurring on the same day as the vaccinations. Dr. Corbier explained that if there had been no evidence of brain dysfunction between July 10, 2000, and August 30, 2000, it would be more difficult to prove that the vaccinations Ashlyn received on July 10, 2000, were the cause of her seizure disorder. Id. at 21-22. Ironically, if the first symptom or manifestation of onset was August 30, 2000, a date which is approximately 51 days postvaccination,

petitioners would face a much more difficult battle in proving that the DTaP, IPV, and/or Hib vaccinations caused Ashlyn's seizure disorder. However, for purposes of calculating the limitations period, it is beyond dispute that there can be only one date of the first symptom or for the manifestation of onset. Shalala v. Whitecotton, 514 U.S. 268, 274 (1995).

2. A Formal Diagnosis Is Unnecessary to Commence the Running of the Limitations Period.

Vaccine Act cases uniformly hold that the 36-month limitations period "does not require a diagnosis of a condition to start the running of the statute of limitations." Goetz v. Sec'y of HHS, 45 Fed. Cl. 340, 342 (1999), aff'd, 4 Fed. Appx. 827 (Fed. Cir. 2001) (stating further that "the occurrence of an event recognizable as a sign of vaccine injury by the medical profession at large, not the diagnosis that actually confirms such an injury in the specific case" triggers the running of the statute of limiations); Setnes v. United States, 57 Fed. Cl. 175, 181 (2003) ("The court is not holding that a medical or psychological diagnosis or verification of the 'occurrence of the first symptom or manifestation of onset' begins the running of the statute of limitations."). Indeed, petitioners concede this well-settled point of law.[33] Pet. Br. at 4. In a similar vein, petitioners also recognize that the Vaccine Act "does not require knowledge that the vaccine caused the symptom or manifestation of onset in order for the

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[33] All references to Petitioners' Brief in Support of Onset Date of August 30, 2000, shall be designated herein as "Pet. Br. at ."

statute of limitations to start running." Id.; see also Childs v. Sec'y of HHS, 33 Fed. Cl. 556, 558 (1995).

Those concessions notwithstanding, petitioners argue that their claim is timely because they "were neither aware, nor should they have been aware, that Ashlyn had a disease or a condition as of July 10, 2000." Pet. Br. at 5. By framing the issue in this manner, petitioners divert the inquiry from its proper focus. The critical point on which the limitations issue is decided is when onset was manifest. The special master is not holding that the parents were obligated to recognize or diagnose their child's disorder from the first moment it occurred. To the contrary, the special master is applying an objective standard as to what the medical community at large would recognize as the first symptom of Ashlyn's seizure disorder. Dr. Corbier testified that the first symptom or manifestation of onset occurred on July 10, 2000, even though petitioners did not fully comprehend what they saw at the time. As the petition and Ms. Markovich's affidavit reflect, petitioners observed the rapid eye blinking episodes, but did not realize they were neurological signs manifesting the initial onset of symptoms until after the August 30, 2000 seizure. The parents' failure to identify Ashlyn's eye blinking episodes as the manifestation of initial onset of an illness or condition is insufficient to postpone the running of the statute of limitations.

3. Pegging Onset to the Repeated Rapid Eye Blinking Episodes, Which Began on July 10, 2000, Does Not Impose a Heavier Burden on Petitioners.

Petitioners essentially ask that the special master toll the limitations period, which began when they first observed the initial onset of symptoms on July 10, 2000. This she cannot do. Brice, 240 F.3d at 1368, 1373-74. The testimony of petitioners' expert has demonstrated that Ashlyn's July 10, 2000 eye blinking episode was the first neurological symptom of Ashlyn's seizure disorder. Contrary to their argument, pegging the date of onset to the eye blinking, as required by statute, does not impose a heavier burden on petitioners. The Vaccine Act does not require that the petitioners know the precise moment that Ashlyn suffered a seizure disorder. Nor are petitioners required to identify one or any combination of vaccines that Ashlyn received as having caused her injury. An objective reading of the statute reveals that Congress did not craft language that required knowledge of a specific vaccine-related injury. Rather, Congress specified that the limitations provision of the Vaccine Act is triggered by the first symptom or manifestation of onset of the injury. Here, the petition, Ms. Markovich's affidavit, and the testimony of Dr. Corbier reflect that the eye blinking episodes began on July 10, 2000. As explained above, Dr. Corbier identified the July 10, 2000 eye blinking episode as the first neurological symptom marking the onset of a vaccine-related injury. Importantly, Dr. Corbier admitted that even if he could not confirm a seizure disorder on July 10, 2000, Ashlyn's symptoms "would at least lead to a suspicion and the need for further questioning and

evaluation." Dr. Corbier stated that the eye blinking could have been either "subtle seizures ... or some type of brain dysfunction." Regardless of the specific neurologic injury flowing from vaccination, Dr. Corbier explained that given that the eye blinking episodes continued over time until the seizure on August 30, 2000, "you can see that there was a progression of symptoms." This testimony conclusively demonstrates that the only possible date of onset is July 10, 2000.

4. The Vaccine Act Does Not Differentiate Between Subtle and Pronounced Symptoms.

In the Vaccine Act, Congress made no distinction between subtle and pronounced symptoms for the date of onset. If Congress had intended such a distinction, the Vaccine Act would contain such language, but it does not and the special master will not engraft such a provision. As respondent correctly points out in his posthearing brief, there are numerous cases where the established first manifestation of symptoms was subtle. For example, in Lynch v. Secretary of HHS, No. 90-3767V, 1992 WL 365457, at *4 (Fed. Cl. Spec. Mstr. Nov. 12, 1992), the special master noted that even though the parents did not recognize it as significant at the time, the first symptom or manifestation of onset was the child's slumping over in a chair, which marked the child's first seizure. Other decisions have noted that brief eye blinking or fluttering constituted the onset of symptoms even though the symptoms were subtle. See Gruber v. Sec'y of HHS, No. 95-34V, 1998 WL 928423, at *8 (Fed. Cl. Spec. Mstr. Dec. 22, 1998), rev'd on other grounds, 61 Fed. Cl. 674 (2004); Lara v. Sec'y of

HHS, No. 90-1655V, 1993 WL 215068, at *13 (Fed. Cl. Spec. Mstr. June 4, 1993). As explained by the Court of Federal Claims in Goetz. "[I]t is clear that Congress intended the cause of action... to accrue upon occurrence of the first symptom of an injury, not upon the first identification of a link between the injury and the vaccination." 45 Fed. Cl. at 342.

5. The Setnes Decision Does Not Apply to the Facts of This Case.

Petitioners urge the undersigned to apply their interpretation of the holding in Setnes v. United States. Setnes, instructive but non-binding Court of Federal Claims precedent, is inapposite here.[34] In Setnes. the injured child, AJ, suffered from autism, a condition that went undiagnosed by his physicians for many months despite their best efforts and years of education and training. 57 Fed. Cl. at 177. Specifically, AJ's behavior changed after his 15-month vaccinations-he made a constant humming noise and was doing a lot of babbling. Id. at 176-77. Other changes in behavior included kicking, screaming, and even instances when AJ ate videotape cardboard boxes. Id. at 177. Despite being examined by his pediatrician and his obvious change in behavior, AJ went undiagnosed for many months. Id. It was not until ten months after the vaccinations in question had been administered that AJ's pediatrician expressed concern that he might suffer from a pervasive developmental disorder. Id. Finally,

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[34] "Special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand." Hanlon v. Sec'y of HHS, 40 Fed Cl. 625, 630 (1998), aff'd, 191 F.3d 1344 (Fed. Cir. 1999).

nearly 16 months postvaccination, AJ was diagnosed with autism. Id.

In order to prevent the dismissal of their petition on statute of limitations grounds, AJ's parents argued that "because of the unique nature of autism spectrum disorder, there can be no 'manifestation of onset' until such time as the medical and psychological professionals verify through reliable medical and psychological means that a constellation of behaviors presented in a specific child meet the criteria for autism spectrum disorder." Id. at 179. Although not accepting all of the parents' arguments, the court agreed that:

> As distinguished from other medical conditions,... the beginning stages of autism cannot be reduced to a single, identifiable symptom. Many of the initial 'symptoms' are subtle and can easily be confused with typical child behavior. Where there is no clear start to the injury, such as in cases involving autism, prudence mandates that a court addressing the statute of limitations not hinge its decision on the 'occurrence of first symptom.'

Id. (footnotes omitted) (emphasis added). The court stated that the onset of AJ's autism was not manifest for a number of months after the first symptoms occurred because the injury was not manifest. Id. at 181. The court reasoned that if AJ's pediatrician were unable to diagnose an injury, then it would be unfair to apply the statute in a mechanical way that required the parents to have greater skill and training than the pediatrician. Id.

In reaching its conclusion, the court reasoned that Congress's use of the word manifest was not surplusage. Id. at 180.

The Setnes court held that "in a situation such as that before the court, where the symptoms of autism develop 'insidiously over time' and the child's behavior cannot readily be connected to an injury or disorder, the court may rely on the child's medical or psychological evaluations for guidance in ascertaining when the 'manifestation of onset' occurred." Id. at 181. The Court further remarked that: "It is one thing to be unaware that an obvious injury or its onset was caused by a vaccination. It is quite another to lack knowledge, through no assignable fault, of the existence of the onset. This is especially true where the treating physician does not associate the behavior as an onset of an injury." Id.

Although not a treating physician, Dr. Corbier identified the rapid eye blinking episodes, which began on July 10, 2000, as a neurological indicator of mild seizure or other brain dysfunction. Although it was not until after the August 30, 2000 seizure that Ashlyn's parents realized that they may have been observing possible subtle seizures beginning on July 10, 2000, that does not alter the reality that those mild seizures or brain dysfunction episodes were manifest. As explained earlier herein, petitioners need not understand the significance of a first symptom, the symptom merely must be manifest. To hold otherwise would open the door to many who would conveniently argue that while they observed certain activity shortly after vaccination that was later explained to be the first symptom or

manifestation of the onset of an injury, because they lacked medical training, they failed to recognize those first symptoms as the manifestation of an injury.

Unlike Setnes, this case does not involve autism. Another distinguishing feature is that in the instant case, petitioners' expert pediatric neurologist testified that the eye blinking episode was part of the same process as the dysfunction that culminated on August 30, 2000 in a seizure. Thus, unlike the child in Setnes. Ashlyn had a clear and defined neurological event-repeated rapid eye movement. There can be no serious disagreement that neurological symptoms are not equivalent to typical childhood behaviors. A pediatrician might well expect to see a young child like AJ babble and kick. However, as Dr. Corbier testified, rapid eye movements would raise his suspicions.[35] In sum, Dr. Corbier's testimony was unmistakable that the rapid eye blinking episodes that began on July 10, 2000, and the August 30, 2000 seizure were all part of the same process. Therefore, petitioners' contention is

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[35] Petitioners' counsel tried to lead Dr. Corbier through a Setnes analysis. However, those efforts were not successful. After being asked whether "the beginning states of epilepsy [can] be reduced to a single identified symptom," Dr. Corbier responded: "Yes, in a sense that instead of what is called a grand mal... seizure, you may have situations where instead of having a full-blown episode, you may have something that is less mild at first, and then may build up into a more conspicuous and remarkable episode, such as a grand mal seizure." Tr. at 11. Thus, Dr. Corbier did make a direct connection between the rapid eye blinking that began on July 10, 2000, and culminated with Ashlyn's August 30, 2000 seizure.

unpersuasive that because they were not so alarmed by Ashlyn's eye blinking episodes as to seek medical attention, the statute of limitations did not begin to run. As described above, this reasoning is not in accord with other Vaccine Act decisions. As the Federal Circuit cautioned in Brice v. Secretary of HHS, courts must be "careful not to interpret [a waiver of sovereign immunity] in a manner that would extend the waiver beyond that which Congress intended. 240 F.3d at 1372-73 (quoting Stone Container Corp. v. United States, 229 F.3d 1345, 1352 (Fed. Cir. 2000)).

Petitioners are devoted and caring parents. That their little girl is afflicted with a terrible condition, which at times is life-threatening, is heart wrenching. Magnifying their pain is the fact that the reason petitioners had their child vaccinated was to preserve her good health, not to jeopardize it. And now, because they filed their petition 50 days too late, they face dismissal of their petition in the very program designed to compensate parents who believe that their child sustained a vaccine-related injury. If another option were available to her, the special master would take it with alacrity. But the special master is constrained by the law written by Congress. The Vaccine Act, contains a specific limitations period which unambiguously states that the clock begins to run on the date of the occurrence of the first symptom or manifestation of onset of injury. Petitioners' evidence proves that although they may not have understood their significance, they nevertheless were aware that the eye blinking episodes began on July 10, 2000.

IV. CONCLUSION

Petitioners bear the burden of proving that the petition was timely filed. Unfortunately for petitioners, the petition, Ms. Markovich's affidavit, the expert affidavits and reports, and the expert testimony at hearing make clear that the first symptom or manifestation of onset of Ashlyn's seizure disorder occurred on July 10, 2000, a date which is more than three years prior to the filing of the August 29, 2003 petition. Therefore, the special master finds that the court does not have jurisdiction to decide the merits of this case and petitioners' claim is DISMISSED for failure to satisfy the statute of limitations.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court is directed to enter judgment dismissing the case as barred by the statute of limitations.

IT IS SO ORDERED.

/s/
Margaret M. Sweeney
Special Master

Noran Neurological Clinic
Suite #210
910 East 26th Street Minneapolis, MN 55404
(612) 879-1000 Fax: (612) 879-0722

ASHLYN MARKOVICH
Female DOB: 05/12/2000 88166/1-NNC

09/20/2001 – Phone Note: having sz/probs on meds
Provider: Traci Matthews RN
Location of Care: Noran Neurological Clinic, P.A.

Home: (952) 233-8692
Work: 952-445-4368 til 10am.
Other:
Last appt:
Next appt:
Provider: Steve Janousek MD
Patient's Home Location of Care: NNC910

September 20, 2001 8:47 AM by: Traci Matthews RN
Mom called – she is getting very fed up. Pt is very irritated. pt having little sz this am (can tell by looking at her eyes, freq eye blinking, head rolls to side and quickly goes back to center–mom can tell it is bothering pt). Will shut her eyes and kind of moan...mom wonders if she might not be experiencing dizziness/blurred vision. Walking was better this am so she gave mysoline (25mg)...also on lmt 25mg bid. Wondering if we shouldn'tconsider getting her off all meds as she seems to be so unhappy, and they don't seem to work anyhow.

September 20, 2001 10:08 AM by: Jen Pierce
Mom called again...mom thinks metabolic panel & uric acid needs to be done today. Having a lot of diarrhea and problems...will have drawn @ St. Francis ASAP...needs orders faxed now. What to order???

September 20, 2001 10:16 AM by: Jen Pierce
Called again...could the Carnitine cause the diarrhea or stomach cramping???

Carnitine can cause stomach cramping and diarrhea
need to do carnitine levels
hold carnitine x3d then restart at ½ dose then get to full dose in 1 wk keep us posted
carnitine may help pt
go to ½ dose of mysoline
September 20, 2001 10:29 AM by: Steve Janousek MD

September 20, 2001 10:42 AM by: Traci Matthews RN
Informed mom–she will go to St. Francis now. faxed lab order

September 21, 2001 8:31 AM by: Jen Pierce
Mom called...she knows her meds are causing a lot of s/e...wakes up happy in the a.m. and as soon as meds are given, she gets very cranky, upset and not herself. Mom is getting somewhat frustrated...knows Ashlyn needs to be on these meds, but it's hard to see her cranky like this.
Labs from yesterday entered below:
Added new observation of SGPT (ALT): 62 (1-50) (09/20/2001 8:47)

Added new observation of SGOT (AST): 49 U/L (09/20/2001 8:47)
Added new observation of ALK PHOS: 307 U/L (09/20/2001 8:47)
Added new observation of BILI TOTAL: 1.9 (0.0-1.5) mg/dL (09/20/2001 8:47)
Added new observation of ALBUMIN: 4.5 g/dL (09/20/2001 8:47)
Added new observation of PROTEIN, TOT: 6.4 g/dL (09/20/2001 8:47)
Added new observation of CALCIUM: 10.1 mg/dL (09/20/2001 8:47)

mayo *Clinical Document Copy*

Ashlyn M. Markovich (5-449-277)
Printed 07-SEP-2003 08:57 by User ID: 10185194

Jan-29-2002 – Consult, Jeffrey R. Buchhalter, M.D., Child & Adolescent Neurology

DEMOGRAPHIC INFORMATION:
Clinic Number: 5-449-277
Patient Name: Ashlyn M. Markovich Age: 20 months
Born: 2000-5-12 Sex: F
Address: 2418 Thrush Street City: Shakopee MN 55379-4413 U.S.A.
Note Date: Jan-29-2002 History Section: NEN #1
Service: PDN Event Type: CON Status: Fnl
Last Printed: Jan-30-2002 10:49:55

REFERRAL:
Timothy D. Johanson, M.D., 510 Southdale Medical Building, 6545 France Avenue South, Edina, MN 55435, (952) 920-9191

CHIEF COMPLAINT/PURPOSE OF VISIT:
ASSISTED BY: Dr. Randa G. Jarrar (127-00910).

Intractable seizures.

HISTORY OF PRESENT ILLNESS:
I had the opportunity of meeting 20-month-old, right-greater than left-handed Ashlyn with her mother. The history was obtained. Extensive outside medical records and neuroimaging reviewed and a neurological examination performed. I concur

with the history, findings, and recommendations of Dr. Jarrar in her note dated today.

In summary, Ashlyn is the full-term poduct of an uncomplicated pregnancy, labor, and spontaneous vaginal delivery. There were no difficulties until first focal onset seizure occurred at 4 months of age. Subsequently, Ashlyn has had a variety of seizures including (1) eye blinking with or without a head nod lasting seconds that can occur hundreds per day, (2) right- or left-sided clonic activity of face and/or leg lasting five to seven minutes, occurring approximately every other day, (3) focal or generalized onset of tonic-clonic seizure lasting greater than ten minutes, requiring hospitalization and intravenous medication. The last occurred two months ago. (4) Right- or left-sided body clonic activity usually in the form of a heavy convulsion, occurring approximately once per week, lasting five to seven minutes.

In the past, Ashlyn has been on carbamazepine, Phenobarbital, Topamax, Lamictal, Keppra, Depakote, zonisamide, Mysoline, Dilatin, vitamin B6, and a ketogenic diet with significant ketosis for one month. She is currently on Felbatol with a Keppra taper and had a transient started less than one week ago with somewhat improved seizures.

Ashlyn had a video EEG session at the Minnesota Epilepsy Group in December of 2001. Her mother is not sure of the results but thinks that most of the seizures started on the left side. MRIs dated August 2001 and November 2000 were reviewed, and I agree they are normal.

Ashlyn's development has been relatively normal with regard to fine and gross motor skills but her speech is at the 9- to 10- month old level. There is no family history of seizures.

REVIEWED PMH, ALLERGIES, SH, FH, MEDICATIONS, AND ROS AS NOTED ON THE CURRENT VISIT INFORMATION FORM, DATED 29-JAN-2002 AND ON THE PATIENT FAMILY HISTORY FORM DATED 29-JAN-2002.

PHYSICAL EXAMINATION:
Height: 80.8 cm (31.8 in). Weight: 10.31 kg (22.73 lb).
BSA: 0.5 M2, BMI: 15.792 KG/M2.
Neurological examination reveals a well-nourished, well-developed, slightly postictal child. Cranial nerve testing revealed no abnormalities. Motor examination revealed normal tone, bulk, and spontaneous movements. She had a mild tremor when reaching for objects.

IMPRESSION/REPORT/PLAN:
#1 Intractable localization-related epilepsy
Ashlyn has had very severe seizures which have not been significantly affected by trials of excellent medications as well as a ketogenic diet. At this ppoint, we discussed a number of options. The only modern anticonvulsant that Ashlyn has not used as yet is vigabatrin which could be obtained from Canada. However, it is unlikely that it would produce dramatic seizure relief. The possibility of an immunologically mediated seizure disorder was discussed. A trial of intravenous immunoglobulin or prednisone could be utilized. The lower side effect

rate of the IVIG was noted with the downside of IV being required. Vagus nerve stimulator is also a possibility as a nonpharmacologic therapy. In terms of epilepsy surgery, we discussed corpus callosotomy if a focal ictal onset cannot be discovered. With regard to the latter, there is no clear evidence that the majority of Ashlyn's seizures are coming from one location. Therefore, we discussed obtaining a SISCOM (subtraction ictal spect coregistered with MRI) in an attempt to find the most epileptogenic zone. It was explained that if Ashlyn's surface recording revealed clear independent hemispheric onsets then this would not be pursued. Ashlyn will be admitted to the Pediatric Epilepsy Monitoring Unit tomorrow to begin her evaluation.

DIAGNOSES:
#1 Intractable localization-related epilepsy

SPECIAL INSTRUCTIONS:
Please send a copy of this note to the family at the home address and to Dr. Johanson.

Margin Code: P5

JRB: kcg Revised: Jan-30-2002 10:49 by lmc
Electronically signed Feb-24-20202 09:48 by J.R. Buchhalter, M.D.

mayo *Clinical Document Copy*

Ashlyn M. Markovich (5-449-277)
Printed 07-SEP-2003 08:57 by User ID: 10185194

Jan-29-2002 – Multi-system Evaluation, Randa G. Jarrar, M.B.B.S., Child & Adolescent Neurology

DEMOGRAPHIC INFORMATION:
Clinic Number: 5-449-277
Patient Name: Ashlyn M. Markovich Age: 20 months
Born: 2000-5-12 Sex: F
Address: 2418 Thrush Street City: Shakopee MN 55379-4413 U.S.A.
Note Date: Jan-29-2002 History Section: NEN #2
Service: PDN Event Type: ME Status: Fnl
Last Printed: Jan-30-2002 10:51:29

REFERRAL:
Timothy D. Johanson, M.D., 510 Southside Medical Building, 6545 France Avenue South, Edina, MN 55435, (952) 920-9191

CHIEF COMPLAINT/PURPOSE OF VISIT:
SUPERVISED BY: Dr. Jeffrey R. Buchhalter (4-7519).

Intractable seizures.

HISTORY OF PRESENT ILLNESS:
Ashlyn is a 20-month-old, right- more than left-handed young lady who is coming in today accompanied by her mother and maternal grandmother for evaluation of intractable epilepsy.

She was a product of a full-term, planned pregnancy. Her mother was 26 years old, gravida 1, para 1. Delivery was vaginal, vacuum-assisted. The pregnancy was unremarkable except for two episodes of dehydration which were accompanied by a drop in the fetus's heart rate but otherwise unremarkable. Birth weight was 7 pounds 2 ounces. No resuscitation was required, and she was discharged to home after two days.

Ashlyn did very well during the first 3 1/2 months of life. On August 31, 2000, she had her first seizure. It started out with jerking of one of the extremities–mom does not recall exactly which one. This was followed by a generalized clonic activity that lasted for 20 minutes. She had basic laboratory testing and a spinal tap at that time which was negative. Two weeks later, she had another similar episode. Since then, she continued to have intermittent seizures. Currently, she has four types of seizures. (1) Repeated eye blinking, either unilateral or bilateral with or without head nodding. This lasts for a few seconds and occurs hundreds of times per day. (2) Right or left clonic movement of the face, arm, and leg. This occurs about every other day. She is not arousable during these episodes and these are quite prolonged, and they never stop without Valium. They typically last about seven minutes, and they occasionally generalize. (3) Generalized seizures with or without focal onset. These occur especially with fever, and they usually last for more then ten minutes. They typically require hospitalization. The last one was two months ago. (4) Partial motor right-sided or left-sided seizures that occur once per

week, and they last for variable periods of time, anywhere between minutes to about an hour.

Since the seizure onset, she was tried on numerous medications. She was tried first on Tegretol for about a week; however, she continued to have very significant, severe seizures during that week. Then she was tried on phenobarb for three weeks. She sustained good levels; however, she continued to have significant breakthrough seizures. She was on Topamax for a period of six months. Her dose was 50 mg twice a day. On Topamax, she had her longest seizure-free period which was nine weeks. The mother says that she was free of the generalized tonic-clonic seizure and the unilateral clonic, motor seizures, but she continued to have the eye-blinking seizures. After nine weeks of relatively good seizure control, she started having breakthrough generalized tonic-clonic seizures so lamotrigine was added. She reached a dose of 60 mg per day but continued to have significant breakthrough seizures. Subsequently, she was tried on the ketogenic diet for one month. She was adequately ketonic on that; however, she did not tolerate it. Mom says she was always hungry and irritable. Then she was tried on Keppra, reached a dose of 1500 mg per day without good control of the seizures. Then she was tried on zonisamide, reached a dose of 100 mg at bedtime and continued to have seizures. Then Keppra was added to the zonisamide without adequate control. Somewhere during these trials, she was put on Dilantin, but the mother does not remember exactly when. While on Dilantin, she continued to have the seizures, and in addition, she developed two drop seizures which she never had without the Dilantin.

She was also given pyridoxine for one month. Most recently, she has been on felbamate. She has been taking that for a month, and she continues to have seizures. Tranxene has been given for the last week. She is currently being tapered off Keppra. Fortunately, she did not develop any side effects to any of the above mentioned medications.

As for investigations, she has numerous EEGs and prolonged monitoring. Her initial EEG showed predominantly right posterior occipital quadrant abnormalities and seizures. However, she underwent prolonged monitoring in September of 2001 which showed poorly organized, slow background. She had multifocal spikes originating from T7, P3, T8, and P8. Several ictal events were preceded by high amplitudes, slowing followed by suppression. The most recent monitoring was in December. We do not have the reports of that monitoring stay. However, mom recalls that she was told that she had several seizures of right- and left-sided onset. She had two MRIs, one in October of 2000 and another in August of 2001, both of which were negative. Her serum amino acids and urine organic acids were checked, and they were within normal.

Despite all these seizures, she is doing well developmentally. Mom thinks that her gross motor and fine motor development is appropriate. She currently can run. She can go down stairs. She is occasionally off balance, especially when she takes large doses of Valium. She has an excellent pincer grasp. She can say eight to ten words. She cannot make sentences. Her speech tends to fluctuate;

however, her development otherwise has been progressing steadily. She was assessed during her most recent hospitalization in December and was found to be developmentally appropriate in terms of growth and fine motor development; however, her speech was at 9- to 12-months level. She moves her upper and lower extremities quite well except following a prolonged focal seizure after which she has Todd's paralysis. She seems to have normal sensation. She can swallow well. She seems to hear well and see well. She has normal bowel and bladder function. She has no history of recurrent fevers. She has good appetite. Ever since starting Felbatol, she has not been sleeping well. However, this responded to melatonin at bedtime.

Numerous outside medical records were reviewed. Her two outside MRIs were also reviewed.

CURRENT MEDICATIONS:
Felbamate 600 mg/5 cc. She takes 4 cc in the morning, 4 p.m, and 3 cc at bedtime.
Tranxene 3.75 mg tablets. She takes 1/4 to 1/2 a tablet twice a day.
Rectal Valium on an as-needed basis.
Keppra 125 mg q.d. This is being tapered off.

ALLERGIES:
None.

PAST MEDICAL/SURGICAL HISTORY:
As mentioned above. She had numerous hospitalizations because of status epilepticus but no significant medical problems otherwise.

SOCIAL HISTORY:
She lives with her parents. Mom is a nurse who works on a part-time basis. Dad works with computers. Vaccinations–she only received her 2-month vaccines. It was thought that the seizures started seven to ten days after the 2-month vaccine so no further vaccines were given. Development as mentioned above. Birth history is as mentioned above.

FAMILY HISTORY:
She is an only child. There is no family history of seizures, mental retardation, or developmental delay. No family history of febrile seizures.

PHYSICAL EXAMINATION:
Head Circumference: 45.0 cm.
Head circumference was 45 cm, on the 5th percentile for age. Mom indicates that her head has always been the 5th percentile for age ever since she was born.
Skin: She had no stigmata of neurocutaneous disease. Wood lamp exam was negative.
HEENT: Head and Neck exam was unremarkable.
Heart: Normal S1, S2, no murmurs.
Lungs: Clear.
Abdomen: Soft with no organomegaly.
Spine: Straight and normal.
Neuro: During the evaluation, she had numerous eye-blinking spells. In between them, she was appropriate for her age. She played with her grandma and played peek-a-boo and waved bye-bye. During the evaluation, she had one complex partial seizure consisting of clonic activity involving the right face and the right upper extremity. This lasted

for about five minutes and was aborted by giving a rectal Valium. Cranial nerves were examined and were within normal. Her pupils were equally reactive to light. Fundi were within normal. She tracked well. Visual fields appeared to be normal to confrontation. Facial, lingual, and palatine muscles were within normal. She appears to have normal hearing. Motor exam, prior to the clonic seizures, she was moving her upper and lower extremities symmetrically and equally; however, there was some weakness for short periods of time following the seizure. Her tone was within normal. Her reflexes were normal and symmetric. Plantars were downgoing bilaterally. Sensory exam appears to be grossly intact. She had no evidence of incoordination. She reached appropriately and adequately. Her gait prior to the seizure was within normal; however, after getting the Valium, she was drowsy and was unable to walk independently.

IMPRESSION/REPORT/PLAN:

#1 Intractable epilepsy

It appears that Ashlyn has an intractable epilepsy syndrome. It consists of seizures of multifocal onset and perhaps some seizures of generalized onset. Her previous EEGs have been nonlocalizing as was her MRI. She failed numerous appropriate drug trials. There are not too many options available at this point; however, we discussed with her the remaining options. In terms of medications, one can try vigabatrin or Gabitril and perhaps give some of the previously tried medications another trial. Topamax seemed to have worked best for her so potentially that can be tried one more time and perhaps Trileptal. We also discussed with mother the

various surgical options including the vagus nerve stimulator, the possibility of focal resective surgery as well as corpus callosotomy. We discussed with her that the likelihood that she will have a respectable lesion is quite small, but it is worthwhile the evaluations since she has been intractable since the onset of her seizures. If the evaluation does not reveal a surgically respectable focus then the next step would be to evaluate her for either vagus nerve stimulator or corpus callosotomy. The risks and benefits of each procedure were discussed with family. At this point, we will admit her to the Epilepsy Monitoring Unit to record some of these seizure and determine whether she would be a candidate for SISCOM. I suspect that then we would be able to record several of her seizures without altering her medications, but if we are unable to then we could start out by tapering of the Tranxene. She will be seen once she is admitted to Saint Marys Hospital.

DIAGNOSIS:
#1 Intractable epilepsy

Margin Code: P5

RGJ:tac Revised: Jan-30-2002 10:50 by lmc
Electronically signed Feb-01-2002 10:09 by R.G. Jarrar, M.B.B.S.

UNITED STATES COURT OF FEDERAL CLAIMS

MICHAEL AND MELISSA MARKOVICH, AS PARENTS OF ASHLYN M. MARKOVICH, Petitioners,	)	
v.	)	Docket No.: 03-2015V
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	)	

Pages: 1 through 28

Place: Washington, D.C.

Date: November 5, 2004

IN THE UNITED STATES COURT OF
FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

MICHAEL AND MELISSA MARKOVICH, AS PARENTS OF ASHLYN M. MARKOVICH, Petitioners,	)	
v.	)	Docket No.: 03-2015V
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	)	

Room 508
Courtroom No. 7
National Courts Building
717 Madison Place, N.W.
Washington, D.C.

Friday,
November 5, 2004

The parties met, pursuant to notice of the Court, at 10:12 a.m.

BEFORE: HONORABLE MARGARET M. SWEENEY
Special Master

APPEARANCES: (Telephonically)

For the Petitioners:

MARK L. KRUEGER, Esquire
Greenhalgh & Hoffman, S.C.
123 Second Street
Post Office Box 41
Baraboo, Wisconsin 53913
(608) 356-2008

APPEARANCES: (Continuing)

For the Respondent:

TRACI R. PATTON, Esquire
U.S. Department of Justice
Torts Branch, Civil Division
P.O. Box 146
Ben Franklin Station
Washington, D.C. 20044
(202) 353-1589

* * * * *

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PROCEEDINGS

(10:02 a.m.)

THE CLERK: The United States Court of Federal Claims is now in session, the Honorable Margaret M. Sweeney presiding in the case of Michael and Melissa Markovich, as Parents of Ashlyn M. Markovich, versus the Secretary of the Department of Health and Human Services, Case Number 03-2015V.

THE COURT: Good morning, counsel. Thank you both for being here this morning, and Dr. Corbier, thank you for appearing by telephone. We are here for an on-site hearing in this case, and just as a housekeeping matter, Mr. Krueger, Petitioner's counsel, has advised me that he intends to file Dr. Corbier's CV, and I understand, Ms. Patton, that you have a copy of that?

MS. PATTON: Yes, I do.

THE COURT: Thank you very much. Would either counsel like to make an. opening statement, or do you want to proceed to the direct and cross of Dr. Corbier?

MR. KRUEGER: That would be fine with me. I don't think an opening statement is necessary.

MS. PATTON: That's fine, Your Honor.

THE COURT: Very good. Let us proceed. Doctor, I have to swear you in, of course. Whereupon,

DR. JEAN-RONEL CORBIER

having been duly sworn, was called as a witness, and was examined and testified as follows:

DIRECT EXAMINATION

BY MR. KRUEGER:

Q Dr. Corbier, this is Mark Krueger again. Good morning.

A Good morning.

Q Could you please state your full name for the record?

A I am Dr. Jean-Ronel Corbier.

Q And, Dr. Corbier, what is your business address?

A My address is 7024 Sydney Curve, and that is in Montgomery, Alabama 36117.

Q And what is your occupation?

A I am a child neurologist.

Q And how long have you been a child neurologist?

A I have been a child neurologist since 2000.

Q And when did you receive your medical degree?

A I received my medical degree in 1995.

Q And are you licensed to practice medicine?

A Yes, I am licensed to practice in the State of Alabama.

(Brief Interruption.)

THE COURT: Doctor, we are having technical difficulties. If you could hold on, please.

(Pause.)

BY MR. KRUEGER:

Q Doctor, have you ever had your license revoked or suspended?

A No.

Q Are you board certified?

A Yes. I am board certified in child neurology.

Q And in this particular case, your resume that I will be filing with the Court and which

you provided, is that your most current curriculum vitae?

A Yes, it is.

Q Do you specialize in -- I assume you specialize in child neurology?

A Yes, I do.

Q Have you ever treated children with seizure disorders?

A Yes, I have treated both individuals and children with seizures.

Q And a seizure disorder is another word for epilepsy?

(Brief Interruption.)

THE COURT: Doctor, can you hear us now?

THE WITNESS: Yes.

THE COURT: All right. Thank you, doctor.

BY MR. KRUEGER:

Q I believe I had asked you that I had assumed that your specialty was child neurology?

A Yes, it is.

Q And I also asked you about treating children with seizure disorders. Is a seizure disorder and epilepsy the same thing?

A Yes, a seizure disorder and epilepsy are the same thing, and actually with a seizure disorder, you can have multiple seizures on a daily basis.

Q Okay. And have you treated children with epilepsy that have been linked to vaccinations?

A Yes, I have treated children with epilepsy that we think have been linked to vaccinations. Yes.

Q Do you have an opinion whether DPT vaccinations can cause seizure disorders?

A Yes, I do have an opinion.

Q And what is that?

A My opinion is that there are susceptible individuals where the DPT vaccination can trigger a seizure disorder, including intractable seizures.

Q And in this particular case did you have a chance to review Ashlyn Markovich's medical records?

A Yes, I have.

Q And those were provided to you by Dr. Marks?

A Yes.

Q What was your purpose in evaluating the medical records? What was your understanding of what you were reviewing?

A Well, the purpose as I understood it was to see if based on the record it was likely or if there was a chance that the vaccine, the DPT, could be related to the patient's seizure disorder.

Q And you did prepare a report based upon your review of the records?

A Yes, based on everything that I had read, I prepared a report. I looked at the history, and the time line, and the clinical seizure disorder that the patient developed.

Q And your report is dated May 19th, 2 004?

A That is correct, yes.

Q And that is the report that we have had filed with the Court in this case is your understanding?

A Yes, it is.

Q And have you personally examined Ashlyn?

A No, I haven't.

Q Do you feel that that in any way impacts your ability to render opinions today?

A No, it should not.

Q Now, in this particular case, I would like for you to look at your report, dated May 19th of 2004. Do you have that in front of you?

A Yes, I do.

Q And you also -- and are your opinions expressed in your report?

A Yes, my opinions are.

Q And that would be on page 3?

A On page 3, yes.

Q Now, during your -- well, let me ask it this way. Do you have an opinion as to the onset date of Ashlyn Markovich' s seizure disorder?

A Yes, I do.

Q What is that opinion?

A The opinion, based on the records that I have reviewed, is that on August 30th, 2000, the patient had a generalized tonic-clonic seizure that lasted at least 20 minutes.

So as of that date, the patient did definitively have documented seizures and that went beyond August 30th, 2000.

Q Now, there is a reference in your report that Mrs. Markovich observed Ashlyn having some periods of time, and even the day of the vaccination, in which Ashlyn was observed blinking her eyes rapidly. Are you aware of that?

A Yes.

Q First of all, what significance do those references to the eye blinking play in rendering your opinions in this case?

A Well, they play an important part, in the sense that from my understanding of the records it seems that on July 10th, 2000, the very day of her vaccinations, there was some blinking of the eye. What is unclear is whether it could have been the beginning of some small unrecognized seizure activity.

That could sometimes be subtle, or it could be some type of beginning of a brain dysfunction that would have culminated to a full-fledged, first full seizure on August 30th.

So my professional opinion is that the time line of when something first started may have started on August 10th, that was due to some type of cerebral dysfunction, and then the results culminated in her having a seizure, a generalized tonic, or grand mal seizure as we call it, on August 30th.

Q Okay. You mentioned August 10th. I believe you meant to say July 10th; is that correct?

A I'm sorry, July 10th.

Q Thank you. Now, you have diagnosed children with seizure disorders?

A Yes, many times.

Q Is eye blinking in and of itself sufficient to warrant a diagnosis of a seizure disorder?

A Not by itself. If we had a situation where someone started having eye blinking for no apparent reason, then we start to ask questions. There are certain things beyond the eye blinking that would raise our level of suspicion more and more in terms of seizure activity, such as observation of a loss of consciousness, ideation, and what we call post-spectral changes.

For instance, if someone has a lot of eye blinking, and then subsequently become very tired or confused, that would be some of the traditional clinical findings that would raise my level of suspicion.

So eye blinking by itself would not lead necessarily to seizures, but would at least lead to a suspicion and the need for further questioning and evaluation.

Q And can the beginning stages of epilepsy be reduced generally to a single identifiable symptom?

A Yes, in a sense that instead of what is called a grand mal, which is a tonic-clonic seizure, you may have situations where instead of having a full-blown episode, you may have something that is less mild at first, and then may build up into a more conspicuous and remarkable episode, such as a grand mal seizure.

Q Are you of the opinion that the eye blinking that would have occurred on July 10th, do you know if, or have an opinion, that that eye blinking episode was in fact a seizure?

A It is hard for me to say definitively that it was or was not a seizure, but it only goes to prove that the eye blinking episodes that started on July 10th were seizures, the only way to be certain would-be to have an EEG done at that time while the eye blinking was going on and correlating it with EEG changes.

Short of that, what we can do is suspect that there are one or two possibilities. One is that the eye blinking could have either been some small seizures, subtle seizures if you will, or there is also the possibility that it could have been some type of brain dysfunction that started at that time, and manifesting as involuntary eye blinking.

And with progressive dysfunction, that person then on August 30th had a full-fledged seizure, and went on to have -- that the patient went on to have more and more seizures, and you can see that there was a progression of symptoms.

Q And that is taking the benefit of hindsight?

A Yes. Yes, because if someone, or if a child, such as in this case, is just having eye blinking, and the child otherwise is happy, and doing well, and not lethargic, it may be hard to -- unless you have a lot of training, it may be hard to even suspect necessarily that these are seizures.

So hindsight is very important, in the sense that, you know, that the seizures started, the full-fledged seizures started on August 30th, and looking back at the eye blinking episodes had been seizures.

Q And as far as your review of the material that you were provided, you are not aware of there being any evidence of seizures between July 10th and August 30th?

A I'm sorry, can you repeat that?

Q Well, that was a bad question, and so I will try to rephrase that. Other than the eye blinking are you aware of there being any other indicators that perhaps this was the predecessor of epilepsy for Ashlyn between July 10th and August 30th?

A Yes, and in terms of the record, that was the only thing that I saw mentioned. was this eye blinking. I did not see any mention of loss of consciousness, or other additional clinical factors.

So the only factors I found in the record was the eye blinking up until August 30th. when the first documented full-blown seizure occurred.

Q Now, in your report, on page 3 your opinions, on Number 2, it says that because of timing, a vaccine related injury could be compatible with this clinical picture. In the event that you have not fully explained that, could you please explain that opinion to the Court?

A Sure. The part that is very suspicious to me is number one, the first full-fledged seizure on August 30th was preceded by the eye blinking that according to the record started on July 10th.

In terms of timing, it appears like there was some type of precipitating event in this case with the vaccine and on that same day you have the eye blinking episodes, irregardless of whether the eye blinking turned out to be some type of cerebral dysfunction or little seizure.

And that they progressed on August 30th to a full-blown seizure, and then according to the record the patient continues having a lot of seizures, and what we would term refractory seizures.

So there have been a lot of evaluations to try to look for alternative diagnoses or causes, and I could not detect any alternative explanations. So looking at that time line, to me, I would say that it was a vaccine related injury causing seizures that could be documented here.

Q And, doctor, just so I am clear, do you claim that the eye blinking all by itself, without any other indicators, would mean that that was a symptom of a seizure disorder?

A The eye blinking by itself could be a seizure, but if there is nothing else going on, I might instead of calling it -- and suggesting that these were actual seizures, I might think instead that there was some type of cerebral dysfunction that might later on lead to a seizure.

But again in order for me to say with an air of confidence that these were actual seizures, I would need maybe some additional factors, such as eye rolling episodes, or alteration of consciousness.

But what seems likely is that because these were involuntary movements at this stage, that there was some type, of dysfunction going on at that time, that may have led up to something more traumatic or conspicuous, such as the seizure of August 30th.

Q And finally, doctor, why do you -- why is it your opinion that the onset date for the seizure disorder for Ashlyn was actually August 30th and not, say, July 10th?

A The episode that occurred on August 30th, I think most neurologists, and even general practitioners, including child pediatricians, based on the medical symptoms, this was obviously a seizure by a clinical description.

The problem with the eye blinking is that even though it could have been, there is not enough perhaps evidence to say for a fact that it was a seizure disorder. But there is a suspicion that needs to be explored further, but there is not enough evidence I think to prove that the eye blinking were seizures.

Q Could the eye blinking have been caused by something other than a seizure?

A Eye blinking could mean different things. Let's say, for example, let's say the child, instead of being two months of age, was 5 or 6 years of age, you might think of a motor tick disorder.

We see it commonly in a condition called Tourette Syndrome that we see in children. But a child that has a tick disorder or has Tourette, that usually starts later at age 4 or 5 years of age, instead of at 2 months.

But to answer your question, apart from having seizures, the child could have involuntary movements due to some type of cerebral dysfunction in the temporal lobe or other parts of the brain that control motor movements.

MR. KRUEGER: I am just going over my notes, doctor, but I think I am close to being finished.

(Pause.)

BY MR. KRUEGER:

Q And again, doctor, just so it is clear, I may have asked this question, and perhaps not in this manner, but your opinion is that the rapid eye blinking by itself would not be evidence of a seizure disorder?

A There is still the chance or the likelihood, though it is not necessarily very high if it is all by itself, but if it is a seizure, you might think of it as a very subtle manifestation or early beginning of a seizure disorder.

But by itself, if you see eye blinking and no other factors, clinically you would not be able to say that these were seizures.

MR. KRUEGER: Thank you, Your Honor, that's all I have.

THE COURT: Before Ms. Patton begins her cross-examination, I just had a question that I meant to ask you, doctor, because I was a little confused by one of your answers to Mr. Krueger. Isn't there a difference between onset and a full-blown seizure?

THE WITNESS: I'm sorry?

THE COURT: Isn't there a difference between a first symptom and then experiencing a full-blown grand mal seizure? What I am getting at is in your professional opinion as a pediatric neurologist wasn't the July 10th eye blinking episode

the first symptom, and not the first full-blown seizure, but the first symptom of the seizures that eventually occurred?

THE WITNESS: That's a good question. When you say the term "symptom" of a seizure --

THE COURT: The first manifestation, the first fact on the picture. The first incident on the radar scope that a doctor would look at and say, you know what, that was the first occurrence, the first fact that something occurred with a child, a body marker, which would explain later that the seizure actually occurred.

But this is when the activity started occurring in the child's body that resulted in the seizure.

THE WITNESS: Yes. To answer that question specifically, the first event that I think everyone can agree upon was an actual seizure was August 30th, and looking back you can say, well, starting July 10th, there was eye blinking.

Potentially, these could have been either one of two things. Either they could have been small seizures leading up to a big one, and that is a possibility.

Conversely, one might say that on July 10th, there were eye blinking episodes that may not necessarily be seizures, but instead some type of cerebral dysfunction that would eventually lead to seizures.

Unfortunately, there is really -- it is hard to -- and again without an EEG to say that these eye movements, involuntary eye movements, were seizures. They could be small seizures, or they definitely could be the onset of something, whether they are small, tiny seizures, building up to a big one, or some type of cordial cerebral dysfunction, manifesting as involuntary movements, that would then lead to a full organized seizure.

THE COURT: Well, our focus today isn't necessary when did the first full-blown seizure occur, but what was the first symptom.

THE WITNESS: The first symptom of a brain dysfunction.

THE COURT: And would you say that the first symptom occurred with the eye blinking episodes that were noted on July 10th, or shortly thereafter?

THE WITNESS: Yes, I think there was some type of dysfunction of some sort that likely started on July 10th, leading to a documented seizure on August 30th.

THE COURT: Thank you. I appreciate your explanation, because I was getting confused by your answer to Mr. Krueger with respect to onset, versus a full-blown seizure. So, thank you. Ms. Patton, I appreciate it.

THE WITNESS: All right.

CROSS-EXAMINATION

BY MS. PATTON:

Q Dr. Corbier, can you hear me?

A Yes.

Q Seizures are not in and of themselves injuries, but they are expressions of an underlying process that is going on; isn't that right?

A I didn't catch the first part.

Q Seizures are not in and of themselves injuries, but they are expressions of some underlying process that is occurring; is that right?

A Well, that is a little bit close, in the sense that they, too, are expressions of something going on, but they could be injurious if they are prolonged.

Q And do you mean they could cause an injury?

A They could cause an injury.

Q And please correct me if I am wrong, but it is my understanding that seizures themselves are expressions of an underlying injury to the brain, or abnormality, or a dysfunction as you have stated before; is that right?

A Yes, that's correct.

Q So that at some point in time a child, or any individual with have either had an injury, or developed the abnormality or dysfunction that gave rise to the seizures?

A There could be an injury or some type of dysfunction. The dysfunction could be genetic in origin, or it could be traumatic, in terms of an insult or trauma.

Q Could eye fluttering be an expression of a dysfunction or abnormality as well?

A Yes.

Q In this case, doctor, does your opinion that a seizure occurred on August 30th that is related to the DPT vaccination, does that rely on something having happened in between July 10th when the vaccine was given, and August 30th, when you say the first full-blown seizure occurred?

A If you are asking -- I'm sorry, can you repeat your question?

Q Perhaps I didn't phrase that well. If nothing had happened in between July 10th and August 30th, would it be your opinion that the vaccine could cause an injury?

A It would be my opinion that it could still do it, but it would be maybe a little harder to prove.

Q Do you rely on something having happened prior to August 30th in rendering that opinion?

A It makes it or raises the level of suspicion for me.

Q And in your opinion the eye fluttering, is that a result of some cerebral dysfunction? I think you may have called it in your opinion multi-focal cordial dysfunction?

A Yes. I think it is likely that it was a dysfunction causing the eye blinking starting on July 10th.

Q And that likely occurred the day of the vaccination?

A Yes, that is my understanding.

Q And then that dysfunction led to the development of the seizure disorder on -- or I don't want to say led to the development of a seizure disorder, but that led to the first full-blown seizure on August 30th?

A Yes.

Q And that this is all part of the same process?

A Process, yes.

MS. PATTON: Thank you, doctor. No further questions.

THE COURT: Do you have any redirect?

MR. KRUEGER: Yes, I do have some follow-up.

THE COURT: All right.

REDIRECT EXAMINATION

BY MR. KRUEGER:

Q Doctor, can you still hear me?

A Yes, I can.

Q Doctor, you have been asked a lot of questions about the eye blinking that occurred on July 10th. Had this seizure on August 30th not occurred, based on just what you know happened on July 10th, would you have concluded that this person was suffering from a seizure disorder?

A Without the August 30th incident occurring?

Q Yes.

A No, it would be real hard to say that. I don't think that would have been a conclusion or finding.

Q So it would be way down the line?

A Way down the line.

Q So you would agree that you linking the eye blinking to the seizure disorder of August 30th is benefitted by the fact that we are not able to look back into time?

A Yes, just looking back, I think we can look at the big picture and try to put things together.

Q But as far as the eye blinking alone, you would not, or it is not your opinion that that alone is evidence of a seizure disorder?

A There is no question that there was a mild seizure, but in terms of a seizure disorder, and seeing signs or symptoms of a seizure disorder, we would want to see signs or symptoms to strengthen that suspicion.

So the choices really are that it could be mild seizures, or that instead of seizures that there could be some subtle cerebral dysfunction that was starting, and will culminate in a more organized seizure activity down the road. So it is hard to sort those two out.

Q Or it could be as Mrs. Markovich thought, that her daughter was tired?

A Well, yes. It is hard to say exactly what it was, and again only to be absolutely certain from a seizure standpoint would be if indeed at that time an EEG was done at that time to correlate the eye blinking.

So there are really a lot of different possibilities neurologically looking at the August 30th event, and then looking back at July 10th, and there are some eye blinking episodes that started on a particular date, and then on August 30th, you have this major seizure, and you have to wonder if there is some type of correlation.

MR. KRUEGER: Thank you. That's all I have.

RECROSS-EXAMINATION

BY MS. PATTON:

Q Dr. Corbier, just to clarify for me, would it be your opinion that the eye fluttering and seizure disorder are both symptoms of a single process caused by an insult to the brain at about the time of the vaccinations?

A Yes, I think that is a likely -- that is a good possibility.

MS. PATTON: Thank you.

THE COURT: Mr. Krueger.

MR. KRUEGER: Nothing further.

THE COURT: Thank you very much, doctor, for being with us.

THE WITNESS: You're welcome.

MR. KRUEGER: Thank you, Dr. Corbier.

THE WITNESS: You're welcome.
(Witness excused.)

THE COURT: Counsel, thank you very much for coming this morning. I appreciate it. Once we have the transcript lodged, it you would please file briefs from 45 days of the filing of the transcript.

Ms. Patton, if you determine that you need any further testimony from mom or dad, let us know, and we can have a supplemental hearing. Do you think at this stage that is a possibility?

MS. PATTON: I think at this stage we are fine. I actually find a mention in the latter set of records that were sent of something having occurred in July, but if we need to go beyond onset to causation, I think at that time I would just request an order decision from you that you are accepting as fact what is included in the affidavit.

So any expert that I may need knows that he must take into account the July 10th to August 30th eye fluttering.

THE COURT: No, I just wanted to make sure that since we have had a status conference yesterday morning at your request, because you were concerned that perhaps you might need testimony from the parents for purposes of briefing this case, I thought -- and as you know, I didn't think it would be necessary.

But if you find or you believe that is true, you can just let me know now, or if you find as you are preparing your brief that you need to have testimony from the parents, let us know, and we can have a supplemental brief telephonic hearing.

MS. PATTON: Thank you, Special Master.

THE COURT: Thank you very much, counsel.

MR. KRUEGER: Thank you.

THE COURT: And we are adjourned.

(Whereupon, at 10:39 a.m., the hearing was concluded.)

REPORTER'S CERTIFICATE

DOCKET NO.: 03-2015V

CASE TITLE: Markovich v. Secretary, HHS

HEARING DATE: November 5, 2004

LOCATION: Washington, D.C.

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Court of Federal Claims.

Date: November 5, 2004

_____

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No. 06-1539

In the Supreme Court of the United States

MICHAEL MARKOVICH AND MELISSA MARKOVICH,
PARENTS OF ASHLYN M. MARKOVICH,
PETITIONERS

v.

MICHAEL O. LEAVITT,
SECRETARY OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the statute of limitations under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-16(a)(2), commences upon the occurrence of the first symptom of an alleged vaccine-related injury, even if the child's parents do not fully appreciate the medical significance of the symptom at that time.

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In the Supreme Court of the United States

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MICHAEL MARKOVICH AND MELISSA MARKOVICH,
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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-17) is reported at 477 F.3d 1353. The opinion of the Court of Federal Claims (Pet. App. 18-42) is reported at 69 Fed. Cl. 327. The opinion of the special master (Pet. App. 43-87) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on February 20, 2007. The petition for a writ of certiorari was filed on May 18, 2007. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Congress enacted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), Pub. L. No. 99-660, Tit. III, 100 Stat. 3755 (42 U.S.C. 300aa-1 *et seq.*), to promote national childhood immunization programs by establishing a tax-based federal compensation scheme for children injured by vaccines, thereby reducing the number of traditional tort actions filed against vaccine manufacturers. H.R. Rep. No. 908, 99th Cong., 2d Sess. Pt. 1, at 3-5 (1986). The Vaccine Act established a National Vaccine Injury Compensation Program (Program), funded by an excise tax on vaccines, to provide compensation for vaccine-related injuries and deaths. See 42 U.S.C. 300aa-10(a), 300aa-15(i); 26 U.S.C. 9510.

Petitioners under the Program may establish a right to compensation in either of two ways. First, the Vaccine Act presumes that an injury was caused by a vaccination, and is therefore compensable, if the person who suffered the injury "sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table," 42 U.S.C. 300aa-14(a); 42 C.F.R. 100.3(a), and "the first symptom or manifestation of the onset or of the significant aggravation" of the injury "occurred within the time period after vaccine administration set forth in the Vaccine Injury Table." 42 U.S.C. 300aa-11(c)(1)(C)(i); see 42 U.S.C. 300aa-13(a)(1)(A). The presumption of causation may be rebutted by evidence that the injury was "due to factors unrelated to the administration of the vaccine." 42 U.S.C. 300aa-13(a)(1)(B). Second, if the injury does not appear in the Vaccine Injury Table, a petitioner may nonetheless obtain compensation by demonstrating, by a preponderance of the evidence, that the injury in fact

"was caused by" a vaccination. 42 U.S.C. 300aa-11(c)(1)(C)(ii)(I)-(II), 300aa-13(a)(1). A petitioner under the Program need not demonstrate that the vaccine was defective or that its manufacturer was negligent.

The compensation available under the Program includes unreimbursed medical expenses, rehabilitation, special education, vocational training, residential and custodial care, special equipment, lost earnings, pain and suffering, and attorneys' fees. 42 U.S.C. 300aa-15(a)-(e). A petitioner dissatisfied with a Program award may reject it and litigate the claim under state tort law, subject to certain limitations. 42 U.S.C. 300aa-11(a), 300aa-21(a). Applicable state statutes of limitation are tolled during the pendency of a petition under the Act. 42 U.S.C. 300aa-16(c).

In the case of a vaccine-related injury for vaccines administered after October 1, 1988, "no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." 42 U.S.C. 300aa-16(a)(2). Petitions initially are reviewed by a special master of the United States Court of Federal Claims. 42 U.S.C. 300aa-12(d)(3). The parties may seek review of the decision of the special master before the Court of Federal Claims, 42 U.S.C. 300aa-12(e)(1), and may appeal from that judgment to the United States Court of Appeals for the Federal Circuit, 42 U.S.C. 300aa-12(f).

2. On July 10, 2000, petitioners' two-month-old child, Ashlyn Markovich, received vaccinations for diphtheria, tetanus, pertussis, polio, and influenza at the Fairview Cedar Ridge Clinic in Apple Valley, Minnesota. Later that day, she experienced an episode in which her eyes

rapidly blinked or fluttered. Petitioners noticed the episode, but assumed that she was simply tired. Pet. App. 3, 21-22 & n.2, 68.

Ashlyn experienced additional eye-blinking episodes, however, in the weeks following the vaccinations. On August 30, 2000, she became unresponsive for 20 minutes and her extremities jerked uncontrollably. Petitioners immediately called 911. At the emergency room, she was diagnosed as having suffered a grand-mal seizure. Pet. App. 3, 22.

Over the next 17 months, Ashlyn continued to suffer seizures almost daily, at times experiencing three or more seizures in a single day. She also suffered episodes in which her eyes rapidly blinked or fluttered "between 150 and 500 times per day." Pet. App. 3-4. Petitioners sought medical care from several hospitals and numerous doctors, but no treatment proved effective in controlling the seizures. *Id.* at 4, 22-26.

On January 29, 2002, a neurologist at the Mayo Clinic in Rochester, Minnesota, evaluated Ashlyn to determine whether her condition would be susceptible to surgical treatment. The neurologist diagnosed Ashlyn as experiencing "four types of seizures: (1) repeated eye blinking; (2) clonic movement of the face, arm, and leg; (3) generalized seizures with or without focal onset; and (4) partial motor seizures." Pet. App. 4 (emphasis omitted); see *id.* at 96 (neurologist report that "[c]urrently, [Ashlyn] has four types of seizures," one of which is "[r]epeated eye blinking, either unilateral or bilateral with or without head nodding," which "lasts for a few seconds and occurs hundreds of times per day"). The neurologist's evaluation also mentioned that "[i]t was thought that the seizures started seven to ten days after

the 2-month vaccine so no further vaccines were given." *Id.* at 100.

3. a. On August 29, 2003, petitioners filed a claim for compensation under the Vaccine Act, alleging that Ashlyn's severe seizure disorder and intractable epilepsy were caused by the vaccinations administered on July 10, 2000. Pet. App. 4, 26. Based on the petition and an affidavit describing Ashlyn's early symptoms, a special master of the Court of Federal Claims conducted an "onset hearing" to determine whether the petition was timely under Section 300aa-16(a)(2). *Id.* at 4-5, 26-27.

At the hearing, Dr. Jean-Ronel Corbier, a pediatric neurologist, testified for petitioners that a neurological dysfunction likely caused Ashlyn's eye-blinking episode on July 10, 2000, and that the same dysfunction likely triggered the seizure on August 30, 2000. Pet. App. 14-15, 26-27, 74-75.[1] According to Dr. Corbier, the eye-

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[1] See Pet. App. 113 ("[M]y professional opinion is that the time line of when something first started may have started on [July] 10th, that was due to some type of cerebral dysfunction, and then the results culminated in her having a seizure, a generalized tonic, or grand mal seizure as we call it, on August 30th."); *id.* at 115 ("[W]ith progressive dysfunction, [following the eye-blinking episodes] that person then on August 30th had a full-fledged seizure, and went on to have * * * more and more seizures, and you can see that there was a progression of symptoms."); *id.* at 117 ("[O]n that same day you have the eye blinking episodes, irregardless of whether the eye blinking turned out to be some type of cerebral dysfunction or little seizure. And that they progressed on August 30th to a full-blown seizure."); *id.* at 118 ("[W]hat seems likely is that because these were involuntary movements at this stage, that there was some type, of dysfunction going on at that time, that may have led up to something more traumatic or conspicuous, such as the seizure of August 30th."); *id.* at 121 ("[O]ne might say that on July 10th, there were eye blinking episodes that may not necessarily be seizures, but instead some type of cerebral dysfunction that would eventually lead to seizures.").

blinking episodes that preceded Ashlyn's first grand-mal seizure "could have been either one of two things": "small seizures leading up to a big one," or "some type of cerebral dysfunction that would eventually lead to seizures." *Id.* at 121. He testified that, although "eye blinking by itself would not lead necessarily" to a diagnosis of a "seizure disorder[]," eye-blinking episodes "would at least lead to a suspicion and the need for further questioning and evaluation." *Id.* at 114.

Following direct examination of Dr. Corbier, the special master asked him: "[W]ould you say that the first symptom occurred with the eye blinking episodes that were noted on July 10th, or shortly thereafter?" Pet. App. 122. Dr. Corbier replied: "Yes, I think there was some type of dysfunction of some sort that likely started on July 10th, leading to a documented seizure on August 30th." *Ibid.* At the close of Dr. Corbier's testimony, the special master asked him to clarify whether it was his opinion "that the eye fluttering and seizure disorder are both symptoms of a single process caused by an insult to the brain at about the time of the vaccinations." *Id.* at 76-77, 128. Dr. Corbier responded: "Yes, I think that is a likely—that is a good possibility." *Id.* at 77, 28.

Based on Dr. Corbier's testimony, the special master found that the first symptom or manifestation of onset of Ashlyn's seizure disorder was the eye-blinking episode of July 10, 2000. Pet. App. 70-78. Because petitioners filed their Vaccine Act petition on August 29, 2003, more than 36 months after the first symptom or manifestation of onset, see 42 U.S.C. 300aa-16(a)(2), the special master dismissed the petition as untimely. Pet. App. 87.

b. The Court of Federal Claims affirmed. Pet. App. 18-42. It held that the special master was "correct[]" in

finding, based on Dr. Corbier's testimony, that the date of onset was July 10, 2000. *Id.* at 33-34. The court distinguished an earlier, nonbinding decision by a judge of the Court of Federal Claims in *Setnes ex rel. Setnes* v. *United States*, 57 Fed. Cl. 175, 180 (2003) (*Setnes*), which involved an allegation of vaccine-related autism, on the ground that Dr. Corbier's opinion did not conflict with contemporaneous medical evaluations of the first symptoms of the injury. Pet. App. 36. The court also rejected petitioners' proposal for a strictly subjective standard for assessing the occurrence of a "symptom," noting that "the statute of limitations in Vaccine Act cases 'begins to run upon the first symptom or manifestation of the onset of injury, even if the petitioner reasonably would not have known at the time that the vaccine had caused an injury.'" *Id.* at 36-37 (quoting *Brice* v. *Secretary of Health & Human Servs.*, 240 F.3d 1367, 1373 (Fed. Cir.), cert. denied, 534 U.S. 1040 (2001)).

c. The court of appeals affirmed. Pet. App. 1-17. It rejected petitioners' argument that the "symptom or manifestation of onset" of injury must be subjectively recognized as such by the parents to commence the running of the Vaccine Act's statute of limitations. *Id.* at 7-16. Instead, the court held, based on the language of Section 300aa-16(a)(2), that an objectively recognizable symptom or manifestation of onset triggers the start of the limitations period, regardless of whether the petitioner appreciated the medical significance of that symptom at the time. *Id.* at 9 (citing *Shalala* v. *Whitecotton*, 514 U.S. 268, 274 (1995)). Finding no error in the special master's conclusion that the eye-blinking episode on July 10, 2000, was the first symptom of "the same injury that culminated on August 30, 2000, in a grand-mal sei-

zure," the court held that the petition was time-barred. *Id.* at 15.

The court distinguished the Court of Federal Claims' decision in *Setnes* on its facts, noting that "[t]he eye blinking episodes here were not so readily confused with typical child behavior over the course of the limitations period as were the symptoms of autism in *Setnes*." Pet. App. 14; see *id.* at 15 ("[A]s distinguished from *Setnes*, the eye blinking episodes were not normal child behavior."). The court also found that the neurologist's report of January 29, 2002, had made clear to petitioners well in advance of the running of the limitations period "that 'repeated eye-blinking' was not only a symptom of seizure activity but also manifested one type of seizure activity." *Id.* at 14. But the court of appeals also criticized the reasoning of *Setnes*, noting that "it effectively reads the Vaccine Act as if the statute of limitations were not triggered until there was * * * a symptom and manifestation of the injury," and that it incorrectly suggests "that a subtle symptom or manifestation of onset of the injury, such as a symptom that would be recognizable to the medical profession at large but not to the parent, would not be sufficient to trigger the running of the Statute." *Id.* at 10-11.

ARGUMENT

Petitioners contend (Pet. 7) that the court of appeals erred in holding that their petition for compensation under the Vaccine Act was untimely. That contention lacks merit. Section 300aa-16(a)(2) provides that the three-year limitations period runs from "the date of the occurrence of the first symptom or manifestation of onset" of the vaccine-related injury. The court of appeals correctly adopted an objective standard for evaluating

whether a medical condition qualifies as a "symptom or manifestation of onset" of a vaccine-related injury, and its decision does not result in an intra-circuit conflict concerning the statute of limitations in Vaccine Act cases. Further review by this Court is unwarranted.

1. In *Shalala* v. *Whitecotton*, 514 U.S. 268 (1995), this Court considered whether a Vaccine Act petitioner can benefit from the presumption of causation for injuries listed on the Vaccine Injury Table even if some symptoms of the vaccine-related injury predated the vaccination. The court of appeals had concluded that the Vaccine Act did not "expressly" require a showing "that the first symptom of the injury occurred after vaccination." *Id.* at 273-274. This Court reversed, holding that the interpretation by the court of appeals "simply does not square with the plain language of the statute." *Id.* at 274. Construing the same phrase used to define the limitations period in Section 300aa-16(a)(2), the Court noted that "a claimant relying on the table (and not alleging significant aggravation) must show that 'the first symptom or manifestation of the onset . . . of [her table illness] . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table.'" *Ibid.* (quoting 42 U.S.C. 300aa-11(c)(1)(C)(i)). By definition, the Court explained, if a symptom or manifestation of the injury occurred before vaccination, then additional symptoms or manifestations after the vaccination "cannot be the first," and cannot "signal the injury's onset." *Ibid.* ("There cannot be two first symptoms or onsets of the same injury.").

In this case, the court of appeals correctly construed the Vaccine Act's statute of limitations in accord with *Whitecotton*. Section 300aa-16(a)(2) provides for a 36-month limitations period that runs from "the date of the

occurrence of the first symptom or manifestation of onset" of the vaccine-related injury. As this Court recognized in *Whitecotton*, the "first symptom or manifestation of the onset" of a vaccine-related injury occurs on the earliest date that the injury results in a symptom or manifestation. See 514 U.S. at 274 (quoting 42 U.S.C. 300aa-11(c)(1)(C)(i)).[2] The court of appeals was therefore correct in holding that "[u]nder the plain language of the Vaccine Act * * * either a 'symptom' or a 'manifestation of onset' can trigger the running of the statute [of limitations], whichever is first." Pet. App. 8-9.

Petitioners do not contest the special master's finding (Pet. App. 70-78), affirmed by the Court of Federal Claims (*id.* at 33-34) and the court of appeals (*id.* at 14-15), that Ashlyn's eye-blinking episode on July 10, 2000, resulted from the same neurological disorder that caused her grand-mal seizure on August 30, 2000. Nor do they dispute that, from an objective medical standpoint, that episode was a "symptom" of the disorder. Pet. 4-5 (conceding that "Dr. Corbier testified that Ashlyn's July 10, 2000 eye blinking episode was an 'objective symptom' of a seizure disorder").[3] Instead, petition-

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[2] Although *Whitecotton* addressed the causation standard in Section 300aa-11(c)(1)(C)(i) and this case involves the limitations period in Section 300aa-16(a)(2), both cases turn on the meaning of the same statutory phrase. As the court of appeals recognized, "[t]here is no principled basis" for construing the phrase differently in those provisions. Pet. App. 13.

[3] As the special master observed, petitioners' Vaccine Act petition relied upon Ashlyn's July 10, 2000, eye-blinking episode as crucial evidence that the vaccinations caused her seizure disorder. Pet. App. 12-13, 77-78. Dr. Corbier also pointed to the close temporal relationship between the vaccinations and the initial eye-blinking episode as important evidence causally linking the vaccinations and her injury. *Id.* at 15.

ers urge this Court (Pet. 6-7) to hold that a medical condition qualifies as a "symptom" of a vaccine-related injury only if the parents subjectively recognize it as evidence of the injury, arguing that the court of appeals reached an "absurd result" because, on the day of the vaccinations, petitioners found the eye-blinking episode "completely uneventful, short in duration and meaningless" except as an indication that Ashlyn was tired.

Petitioners' proposed standard finds no support in the text of Section 300aa-16(a)(2). The Vaccine Act uses the term "symptom," which in the context of this case refers to observable physical characteristics of the child, not the parents' appreciation of the medical significance of those characteristics. As the court of appeals recognized, "[a] symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury." Pet. App. 9. That a medical phenomenon does not lead to parental appreciation of the significance of the event does not preclude its classification as a symptom.

Petitioners' proposed exclusion of objective symptoms is particularly implausible in light of the distinction drawn in Section 300aa-16(a)(2) between a "symptom" and a "manifestation of onset" of a vaccine-related injury. The term "manifestation of onset" refers to a medical condition "more self-evident of an injury" than a symptom. Pet. App. 9 (noting that a manifestation of onset may refer to "significant symptoms that clearly evidence an injury"). The Vaccine Act makes clear, however, that the limitations period runs from the occurrence of the first symptom *or* manifestation of onset. 42 U.S.C. 300aa-16(a)(2). The court of appeals correctly held that the limitations period runs from the first

symptom of a vaccine-related injury, whether or not the parents subjectively appreciate its significance at the time.[4]

2. Petitioners also argue (Pet. 8-15) that the decision of the court of appeals conflicts with the decision of the Court of Federal Claims in *Setnes ex rel. Setnes* v. *United States*, 57 Fed. Cl. 175, 180 (2003), resulting in inconsistent standards for autism cases and all other cases. That contention is mistaken.

In *Setnes*, the Court of Federal Claims acknowledged that, under Section 300aa-16(a)(2), the occurrence of either the first "symptom" or "manifestation of onset" triggers the commencement of the limitations period. 57 Fed. Cl. at 179. The court noted, however, that "the beginning stage of autism cannot be reduced to a single, identifiable symptom," and that "[m]any of the initial 'symptoms' are subtle and can easily be confused with typical child behavior." *Ibid.* The court therefore carved out an unwritten exception to the limitations period, reasoning that "[w]here there is no clear start to the injury, such as in cases involving autism, prudence mandates that a court addressing the statute of limitations not hinge its decision on the 'occurrence of the first symptom.'" *Ibid.* (quoting 42 U.S.C. 300aa-16(a)(2)).

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[4] Even if the statutory text were ambiguous, the statute of limitations should be narrowly construed because the Vaccine Act is a limited waiver of the sovereign immunity of the United States. Pet. App. 15; see *Brice* v. *Secretary of Health & Human Servs.*, 240 F.3d 1367, 1370 (Fed. Cir.), cert. denied, 534 U.S. 1040 (2001); *Block* v. *North Dakota ex rel. Bd. of Univ. & Sch. Lands*, 461 U.S. 273, 287 (1983) (because "a statute of limitations * * * constitutes a condition on the waiver of sovereign immunity," courts "must be careful not to interpret it in a manner that would extend the waiver beyond that which Congress intended") (internal quotation marks and citation omitted).

The *Setnes* decision is not binding on the United States Court of Appeals for the Federal Circuit. Pet. App. 8. Indeed, it is not binding even on other judges of the Court of Federal Claims. See, *e.g.*, *Vessels* v. *Secretary of the Dep't of Health & Human Servs.*, 65 Fed. Cl. 563, 569 (2005) ("[T]he decisions of one judge of this Court have no binding effect on the other judges."). Petitioners are therefore incorrect in asserting (Pet. 8) that "as the law exists," autism petitions are subject to a more generous statute of limitations. Decisions of the Federal Circuit are binding on the Court of Federal Claims, and the Federal Circuit has now interpreted the Vaccine Act's statute of limitations in this case. Accordingly, if there is any tension between the Court of Federal Claims' decision in *Setnes* and the Federal Circuit in this case, the latter presumably controls.

Further, the statutory analysis in *Setnes* is incorrect. As the court of appeals recognized, "[a] significant problem with the rationale of *Setnes* is that it effectively reads the Vaccine Act as if the statute of limitations were not triggered until there was appreciable evidence showing a symptom *and* manifestation of the injury." Pet. App. 10. Section 300aa-16(a)(2) provides, however, that the limitations period runs from the first symptom *or* manifestation of onset. *Ibid.* ("The use of the words 'first' and 'or' require that the statute of limitations commence with whichever event (i.e., symptom or manifestation of onset) occurs first."). The Court of Federal Claims erred in *Setnes* in believing that its own sense of "prudence" justified an unwritten exception to that unambiguous text. Cf. *Brice* v. *Secretary of Health & Human Servs.*, 240 F.3d 1367, 1372-1374 (Fed. Cir.) (holding that equitable tolling is unavailable for Vaccine Act petitions, based on Section 300aa-16(a)(2)), cert. denied,

534 U.S. 1040 (2001). The rationale of *Setnes* also conflicts with this Court's decision in *Whitecotton*, which "emphasiz[ed] that *any* observable 'symptom or manifestation' may be the first evidence of injury" and "did not require that a petitioner appreciate the significance of that evidence." Pet. App. 12 (quoting *Whitecotton*, 514 U.S. at 274). In any event, the court of appeals has not yet had an opportunity to review the decision of the Court of Federal Claims in *Setnes*. Pet. App. 38 n.13. The court of appeals should be afforded the opportunity in the first instance to determine whether *Setnes* can be reconciled with the court's decision in this case.

Finally, petitioners could not prevail even under the approach of *Setnes*. That case involved symptoms of autism, such as humming, babbling, and kicking and screaming, so indistinguishable from ordinary child behavior that even "contemporaneous medical evaluations" did not recognize them as symptoms of a medical condition. 57 Fed. Cl. at 181. In this case, by contrast, the repeated episodes in which Ashlyn's eyes rapidly blinked or fluttered "were not so readily confused with typical child behavior." Pet. App. 14; see *id.* at 15 ("[T]he eye blinking episodes were not normal child behavior."). Although petitioners argue that Ashlyn's eye fluttering was recognizable as a symptom of her seizure disorder only in hindsight, see *Setnes*, 57 Fed. Cl. at 180, Dr. Corbier testified that the eye-blinking episodes alone "would at least lead to a suspicion and the need for further questioning and evaluation." Pet. App. 114; see *id.* at 14-15. Thus, even if the reasoning of *Setnes* were correct, it would not assist petitioners.[5]

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[5] Petitioners also argue (Pet. 20-22) that the decision of the court of appeals conflicts with the decision of a special master affirmed on

As the court of appeals observed (Pet. App. 14), the Mayo Clinic neurologist's evaluation of January 29, 2002, made clear to petitioners "that 'repeated eye-blinking' was not only a symptom of seizure activity but also manifested one type of seizure activity." One report also drew an explicit connection between Ashlyn's seizures and the eye-blinking episodes that preceded her first grand-mal seizure: "[i]t was thought that the seizures started seven to ten days after the 2-month vaccine so no further vaccines were given." *Id.* at 100. As of the date of that evaluation, petitioners still had more than 17 months, until July 10, 2003, to file a petition for compensation under the Vaccine Act. Because they waited to file until August 29, 2003, their petition was untimely, and the court of appeals correctly affirmed the decision to dismiss it.

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appeal in *Bradley* v. *Secretary of the Dep't of Health & Human Servs.*, 991 F.2d 1570 (Fed. Cir. 1993). In that case, however, the special master found only that the mother's testimony was not credible and that, in light of conflicting medical testimony, the petitioners had failed to prove by a preponderance of the evidence that those conditions were symptoms of her seizure disorder. *Id.* at 1574-1575. The court of appeals affirmed, holding that those findings were not arbitrary and capricious. *Ibid.* Contrary to petitioners' contention (Pet. 22), *Bradley* does not stand for the proposition that "to establish an onset of injury to prove a table injury claim seems to require contemporaneous medical documentation."

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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JULY 2007

No. 06-1539

In The Supreme Court of the United States

MICHAEL MARKOVICH, et ux.,
Parents of Ashlyn M. Markovich,

Petitioners,

v.

MICHAEL O. LEAVITT,
Secretary of Health and Human Services,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY TO BRIEF IN OPPOSITION

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RESPONDENT'S RELIANCE ON *WHITECOTTON* IS NOT PERSUASIVE.

Respondent contends that *Shalala v. Whitecotton*, 514 U.S. 268 (1995), supports its position that further review of this case by this Court is unwarranted. However, the *Whitecotton* ruling is limited in nature and does not apply to the case at hand.

Whitecotton stands for the proposition that you cannot have two first symptoms or onsets of the same injury. A claimant, to make out a prima facie case of a table injury claim, must have evidence of symptoms of an injury during the table period as well as a showing of no evidence of the injury appearing before the vaccination. *Id.* at 274. Respondent contends that the case at hand is applicable to the facts in *Whitecotton* by claiming that the eye blinking episode shortly after the immunization which was attributed to Ashlyn Markovich being tired was the first symptom and, the August 30, 2000, grand-mall seizure was the second symptom. The Respondent goes on to argue that, based upon the *Whitecotton* holding of not being able to have two first symptoms, r this Court is required to dismiss the Markovich's claim. Respondent's argument is misplaced.

First, *Whitecotton* was limited in nature. *Id.* at 278. *Whitecotton* involved a table injury claim and those types of claims in which evidence of the

same injury exists both before the vaccination and within the timeframe set forth in the table. Under those circumstances, *Whitecotton* may be argued to prevent a claimant from proceeding.

Also, Margaret Whitecotton was born with a condition known as "microcephly", which is a known symptom or evidence of encephalopathy. It was the claim of encephalopathy that *Whitecotton* claimed to have occurred within the timeframe set forth in the table. As a result of the symptom or injury being in existence prior to the vaccination as well as within the timeframe set forth in the table, the claimant was not able to proceed with a table injury claim. *Id.* at 275-276.

In *Whitecotton,* the claimant was well aware of the condition of their daughter both prior to the vaccination as well as aware of the injuries allegedly caused by the vaccination at the time the events occurred. In *Whitecotton*, there was a medical diagnosis as well as specific knowledge of and awareness of the injury by the parents. Neither exist in the case at hand. *Whitecotton* is limited to table injury claims and pre-vaccination injuries. There is no rational basis for extending the *Whitecotton* decision to the case at hand. *Whitecotton* is not persuasive as support for Respondent's position.

CONGRESS COULD NOT HAVE INTENDED WHEN IT ENACTED THE NATIONAL CHILDHOOD VACCINE ACT OF 1986 THAT THE 36 MONTH STATUTE OF LIMITATIONS IS TO BEGIN RUNNING UPON OBSERVATION OF A NORMAL CHILDHOOD ACTIVITY.

Every prior case brought before this Court as well as the lower courts have involved fact situations where the parents were aware of an injury of some type to their child within the applicable statute of limitations period. No case to date has presented a fact pattern where the statute of limitations has been held to start because of an event considered normal childhood activity. On or about July 10, 2000, the date the lower courts determined to be the start of the statutes of limitations, the only evidence of an injury was tiredness. No prior decisions concerning the start of the statute of limitations used a normal activity as a triggering event.

Dr. Corbier testified that eye blinking in and of itself was insufficient to warrant a diagnosis of seizure disorder. App., *Infra*, 114. Dr. Corbier testified before the Special Master that his opinions were benefited by hindsight. *Id.* at 115-116. Dr. Corbier opined that without the seizure of August 30, 2000, based on just what happened on July 10, 2000, there would have been no conclusion or finding of a seizure disorder. *Id.* at 126. Finally, Dr. Corbier testified his linking the eye blinking episode of July 10, 2000, to the seizure disorder of August 30, 2000, was benefited by hindsight. *Id.* at 126-127.

The eye blinking episode by itself warrants no diagnosis by a professional nor did it give Mr. and Mrs. Markovich a basis to conclude anything other than that their daughter was tired. No diagnosis of any injury could have been made based solely on that event without the benefit of hindsight. The episode was a non-event in both the eyes of the claimants as well as the medical community.

If Congress intended to help parents with children inflicted with serious, disabling injuries and even death because of adverse reactions to vaccinations, Congress could not have intended to apply such a rigid, inflexible and unreasonable standard to determine when the statute of limitations begins to run. The current standard as determined by the lower courts in this case is unreasonable, impractical and cannot further Congress' intent as set forth in the National Childhood Vaccine Injury Act of 1986.

CONCLUSION

For the reasons set forth by Petitioners, their Petition for a Writ of Certiorari should be granted.

Respectfully Submitted,

Date: September 14, 2007

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